ULTRASONIC CAPSULOTOMY

IN CATARACT SURGERY

A THESIS

by

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(BSc)

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SYNOPSIS

The human lens has two functions to fulfil. It has to transmit light and it has to change its shape according to the requirements of the accommodative process. These functions are determined respectively by the optical and mechanical properties of the lens. It is well documented that cataracts contribute to the gradual changes of the lens matrix properties. The fact is that loss of transparency due to cataract is a universal phenomenon occurring in 70% of the population over 70 years of age and that the only effective treatment for cataracts is its operative removal.[12]

In cataract surgery, *anterior capsulotomy* is a highly defined and crucial procedure. It involves creating a circular opening in the lens by incising the anterior surface of the lens capsule. This gives access to the lens cortex which is then extracted and replaced with a permanent plastic lens. The most popular capsulotomy technique involves tearing the capsule in a circular fashion using forceps. However, there are many potential problems to this technique such as : it is difficult to master, it takes a long time to perform and above all, it runs the risk of creating tears on the periphery of the opening. Since the capsule is retained post-operatively and acts as a support and centralisation of the artificial lens, it is necessary that the integrity of the capsule remain intact. Since anterior capsulotomy is an unpredictable procedure in cataract surgery, there is a definite need for a surgical device that can perform a reliable incision on the capsule.

Using ultrasound to perform a capsulotomy is an innovative technique and its application has to be thoroughly investigated. The investigation includes a numerical and experimental analysis of the lens capsule. The numerical analysis shows that the lens capsule reaches states of resonance at frequencies above 80 kHz. It is at resonance that the capsule oscillations are increased and the cellular bonds are strained and broken. Attempts were made to perforate the human lens capsule using experimental

piezoelectric transducer systems operating at resonance frequencies of 81.6, 106 and 187 kHz. Although each ultrasonic system was able to denature the lens cortex, a perforation of the lens capsule was only achieved at a frequency of 81.6 kHz. However, the perforation was irregular and exhibited several tears. This result is not acceptable as one of the main design requirements is to produce a capsulotomy that has a smooth and continuous margin. The amplitudes for the higher frequencies were inadequate to strain and break the capsule, even when the crystals were driven at their maximum voltage of 400 Volts.

The present investigation proves that it is highly unlikely that an ultrasonic tool can be designed within a safe margin of frequencies and voltages. As long as no other alternative method is devised, surgeons will have to contend with the occasional complication of radial tears that occur during anterior capsulotomy using current anterior capsulotomy techniques.

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1.3 ANTERIOR CAPSULOTOMY

The birth of phacoemulsification in its modern and microsurgical version has revolutionised cataract surgery. However, *anterior capsulotomy* has not been as successful in its amendments. Anterior capsulotomy is a surgical procedure which creates a circular opening in the lens through an incision on the anterior surface of the lens capsule. The integrity of this capsular opening is essential to facilitate cataract surgery as it serves as support and centralisation of the implanted IOL. Therefore, anterior capsulotomy of the lens constitutes one of the most crucial steps in cataract surgery. If the procedure is performed well, the rest of the cataract operation can go very smoothly. If done poorly, the anterior capsulotomy can foul up every subsequent step of the operation.

Creating the perfect capsulotomy is in itself very difficult. Most surgeons aim for a capsular opening that is smooth, continuous and ideally circular as shown in Fig. 7. However, the technique to achieve this remains elusive. The number of techniques that have been devised to perform an anterior capsulotomy testifies to the difficulty and frequent inadequacy of the procedure.

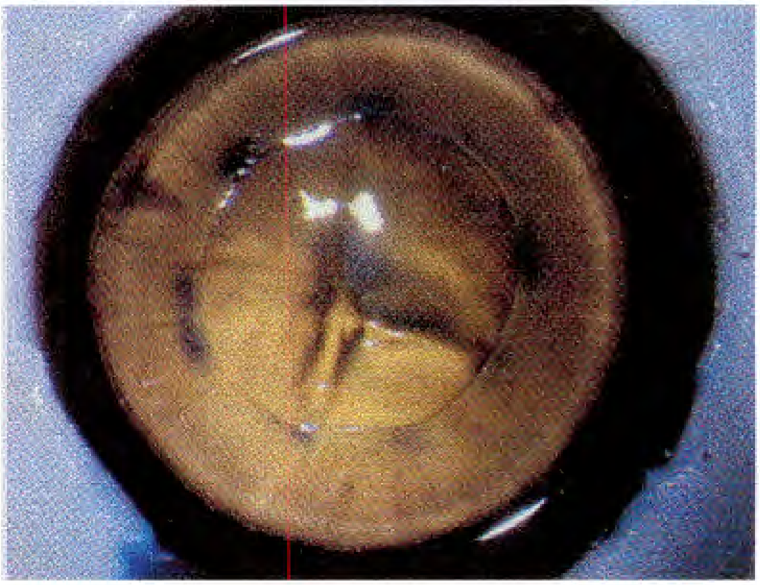


FIG. 7 THE DESIRED CAPSULAR OPENING [4]

1.3.1 VOGT AND CAN-OPENER TECHNIQUES

A technique popularised by Vogt[52] used a toothed forcep to grasp and rip out a part of the anterior capsule, but this severely traumatised both the endothelium and the zonules. The technique was almost universally replaced by the can-opener technique whereby a cystotome creates multiple, circularly interconnected cuts on the anterior capsule as illustrated in Fig. 8. Although both these techniques fulfil the aim of removing the central part of the anterior capsule, they prove to have one major disadvantage : manipulations during phacoemulsification result in the extension of tears on the periphery of the capsulotomy. It is a common occurrence that these tears extend towards the capsular equator and beyond into the posterior capsule. This loss of integrity of the lens capsule complicates the course of the operation.

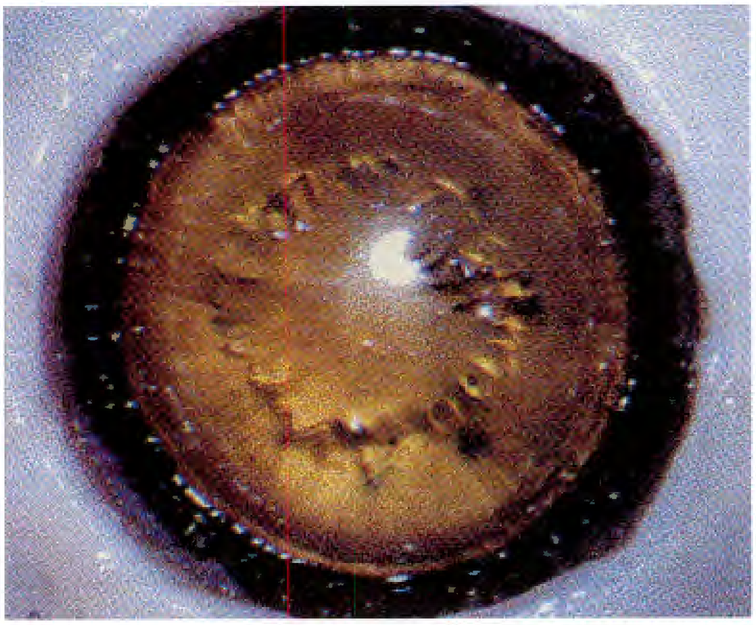


FIG. 8 CAN-OPENER TECHNIQUE [4]

1.3.2 CAPSULORHEXIS TECHNIQUE

In 1984, Gimbel and Neuhann[23], independently developed a technique called 'Continuous Curvilinear Capsulorhexis' or CCC that essentially consists of tearing rather than cutting out a central window on the anterior lens capsule. The tear is brought around the entire circumference, resulting in a tear with no beginning or end or an outward pointing edge. The sequence of steps in CCC is illustrated in Fig. 9.

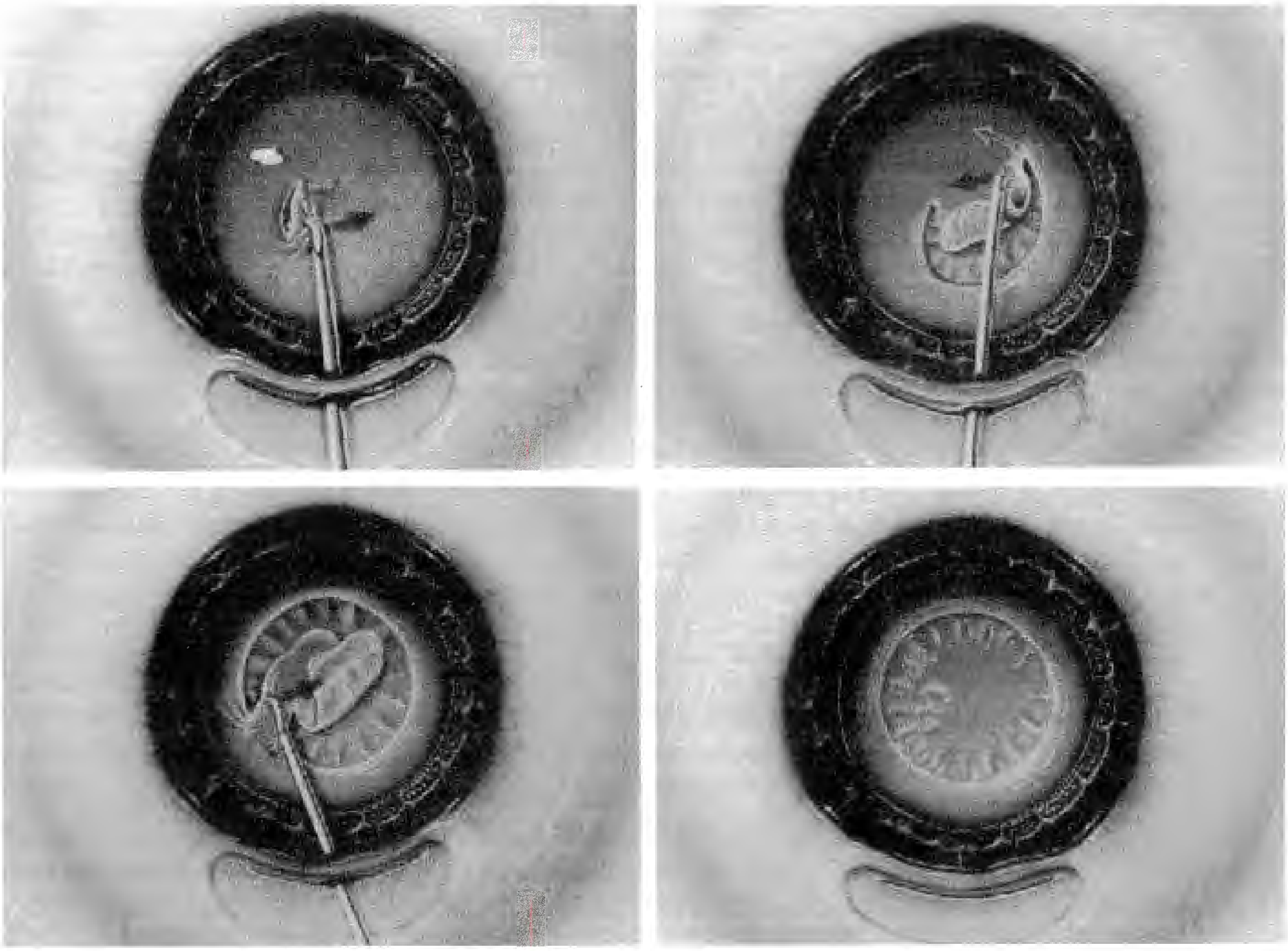


FIG. 9 STANDARD TECHNIQUE FOR CONTINUOUS CURVILINEAR CAPSULORHEXIS [23]

This technique has been an important step forward in cataract surgery. Many surgeons are making the transition to capsulorhexis (CCC) based on clinical observation at surgery and postoperative follow-up. The Leaming[35-40] studies, illustrated in Fig. 10, indicate that the preference for the use of CCC increased from 18% in 1988 to 94% in 1996. Capsulorhexis has proven to be the most reliable and stable method of opening the anterior capsule to date.

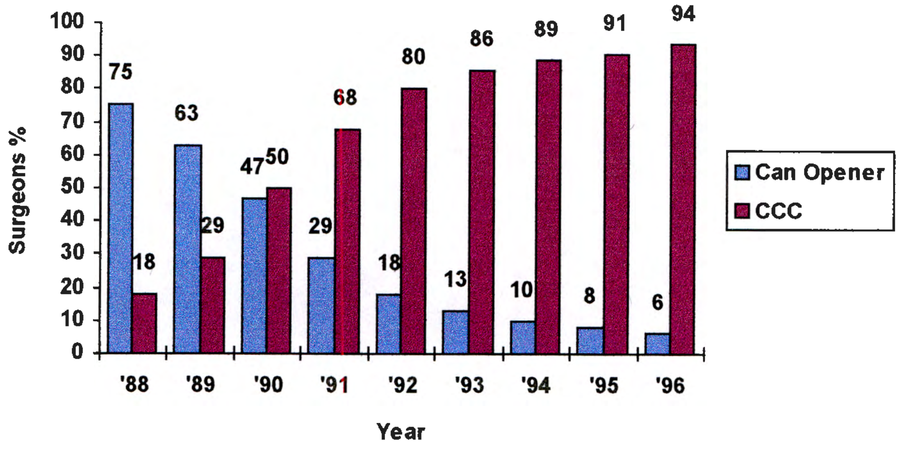


FIG. 10 THE TRENDS IN ANTERIOR CAPSULOTOMY TECHNIQUES

The advantage of the CCC technique has been discussed by several authors in recent years. CCC has shown to produce a circular hole in the capsule with a continuous and smooth margin.[4,52] This opening is resistant to radial tears even when stretched during surgical manipulations such as lens removal or IOL implantation.[2,4,52] Other advantages include the absence of irregular capsular tags or flaps that may interfere with surgery;[2,23,52] the preservation of supporting zonules;[23,24] and furthermore, CCC makes any size of capsular opening possible. These are the main advantages that ensure a secure and permanent capsular bag for the fixation of IOL implants.

The greatest obstacle to this trend is the difficulty that novices have in performing CCC. This procedure requires surgical skill that can be demanding and it has been difficult to teach because of the relatively poor understanding of the forces at work in its performance.[2] If the CCC is done poorly, it may be associated with unpredictable tears during its creation as shown in Fig. 11. The integrity of the capsular opening is therefore lost due to the radial tears and this may result in the decentralisation of the IOL. Another disadvantage of the CCC is that the exact size of the opening is difficult to control.[42] A large opening runs the risk of engaging the zonules and subsequent peripheral tears. A small opening exposes the capsular edge to a greater risk of damage from the ultrasonically oscillating phacoemulsification probe, leading to possible tear formation.

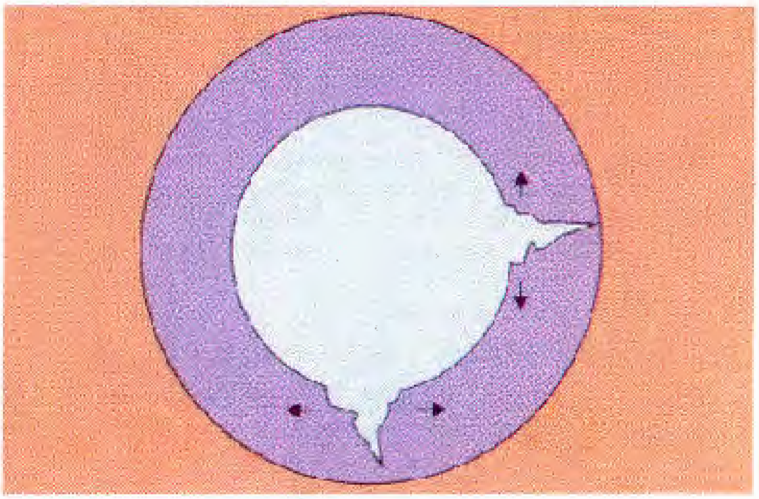
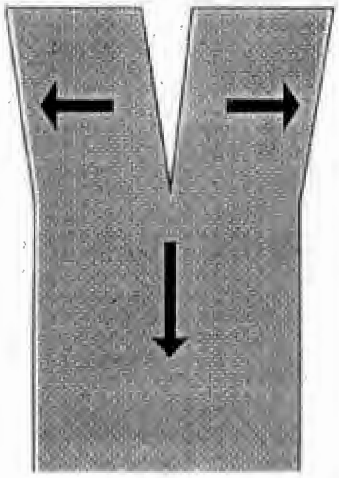


FIG. 11 DISTRIBUTION OF FORCES AT TEARS ALONG THE CAPSULOTOMY MARGIN [11]

1.3.3 PHYSICS OF ANTERIOR CAPSULOTOMY

The surface of the lens on which a capsulotomy is performed is round and convex anteriorly. While still intact, the anterior capsule is stable and taut as a result of pressure exerted against it by the lens contents. This pressure results in an anteriorly directed force, in addition to the radial forces created by the radial insertion of the zonular fibres. Once the anterior capsule is breached and a tear initiated, these forces encourage a capsulorhexis to tear toward the equator as the surgeon attempts to direct it in a circular fashion. The surgeon is then able to tear the capsule in two different manners as illustrated below in Fig. 12 and in Fig.13. The first manner is to stretch it until the force exerted exceeds the resistance of the membrane and the second manner is to exert a shearing force perpendicular to its plane. These two methods require different magnitudes of force and direction and result in very different effects. If the resulting capsulotomy has an irregular and serrated opening, stress concentrations lead to tears along the capsule. Only if the capsulotomy has a continuous smooth margin, can the remaining capsule stay stretched during nucleus extraction as if there was no hole present.

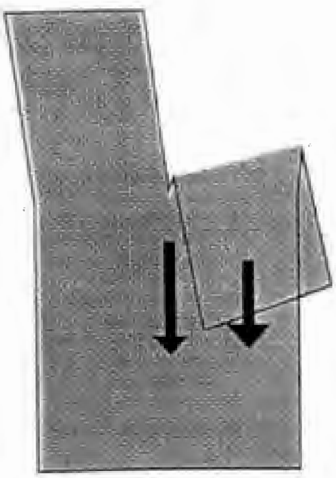
TEARING BY STRETCHING



- The force is distributed over a large area.
- The force is in the plane of the maximum resistance of the material.
- The force must be directed perpendicular to the desired direction of tearing.
- **Once started, this type of tear will uncontrollably extend.**

FIG. 12 CREATING A CAPSULOTOMY BY STRETCHING THE CAPSULE [2]

TEARING BY SHEARING



- The force is concentrated at the point of tearing.
- The force is in the plane of least resistance of the material.
- The force must be directed parallel to the desired direction of tearing.
- **Once started, this type of tear will proceed slowly and can easily be controlled.**

FIG. 13 CREATING A CAPSULOTOMY BY SHEARING THE CAPSULE [2]

1.3.4 BIOMECHANICS OF ANTERIOR CAPSULOTOMY

The lens capsule and zonules are elastic structures that can stretch when an external force is applied. The stretching of the anterior capsulotomy is clinically important during the removal of lens substance or implantation of the IOL through an anterior capsulotomy. When the anterior capsule is undergoing mechanical deformation during nucleus expression, stress accumulates in the tissue and at a certain level of stress accumulation, the capsule tears. Numerical and experimental studies conducted on the elasticity of capsulotomy margins are discussed below.

NUMERICAL INVESTIGATION

Krag[32] presented a finite element model evaluating the risk of tear formation during nucleus expression. The computer model determined the stress distribution in the anterior capsule during nucleus expression for different openings. The lens was modelled as 10 mm in diameter and 20 μm in thickness. Computer simulation was performed on 5.5 mm diameter capsulotomies for the following cases :

- a smooth margin
- a triangular flap directed centrally
- a circular margin with two incisions

The resulting colour plots of the resulting von Mises stress are shown in Fig. 14. The blue colours represent areas of low stress and the red colours represent areas of high stress above breaking point (ultimate tensile strength). The plots indicate that the stress distribution of a smooth capsulotomy is uniform and low. A capsulotomy with a triangular flap exhibits low stress accumulation at the flap and therefore does not increase the risk of tear formation. The stress distribution of a capsulotomy with two incisions shows high stress accumulation at these point. The force required to extend the tear is always less than the force required to stretch the elastic capsule suggesting a serious risk of tear extension. The numerical analysis postulates that a smooth capsulotomy edge has the highest resistance to tearing when stretched.

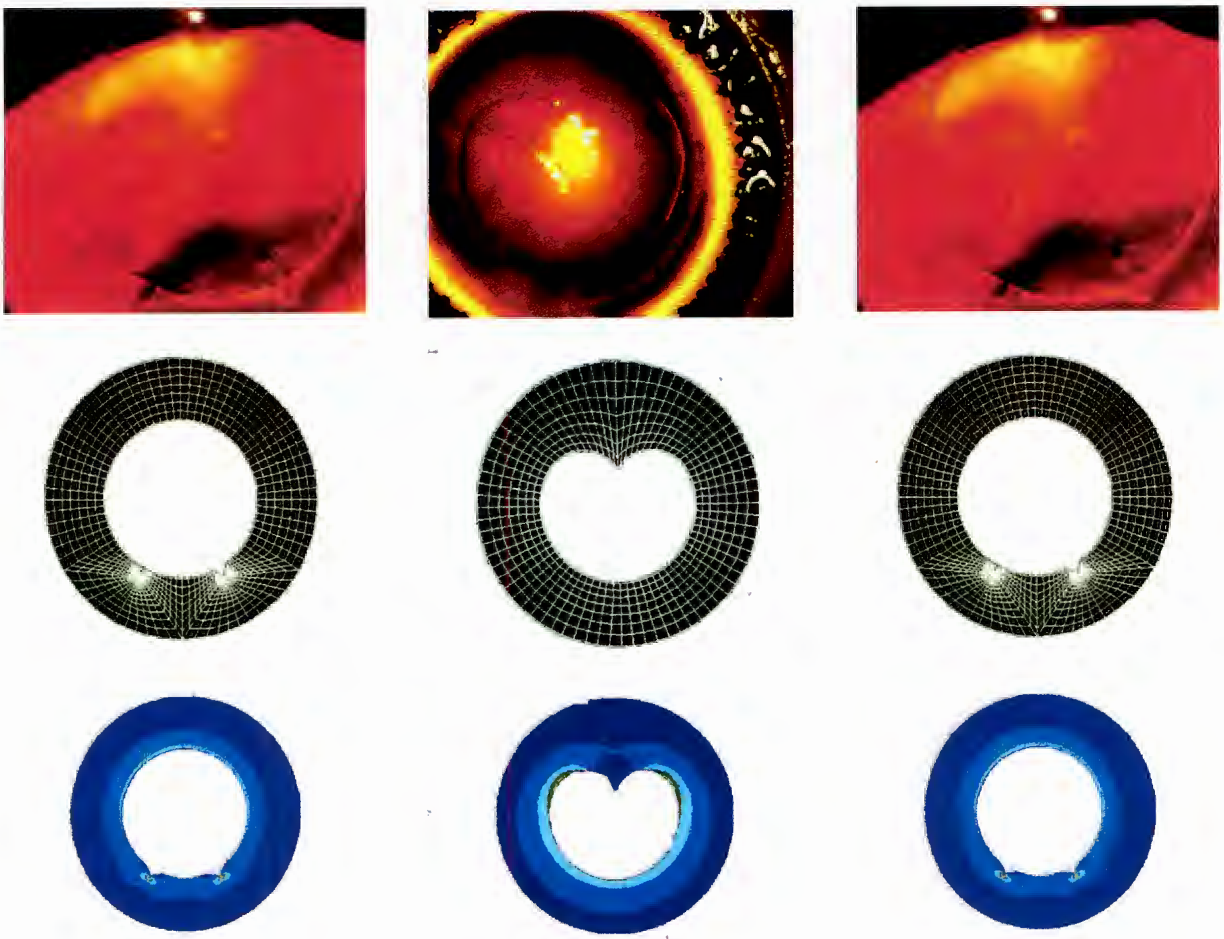


FIG. 14 COMPUTER SIMULATION OF NUCLEUS EXPRESSION [32]

A) HUMAN LENS

B) ANTERIOR CAPSULE MODEL

C) PLOT OF STRESS DISTRIBUTION

EXPERIMENTAL INVESTIGATION

It is important to know the magnitude of the forces that can be tolerated by each capsulotomy. The elastic properties of the circular capsular openings, are well known and are the subject of several studies.[5,6,42] These studies was conducted on the maximal capability of the capsule to stretch before rupture.

The biomechanical properties of the capsulotomy edge following CCC has been quantified by Assia[5,6]. Using a capsular stretch test[♣], he was able to find a highly significant linear correlation between the circumference at rupture (Cr) and the circumference of the capsulotomy (Cc). The ratio obtained was Cr/Cc = 1.56. The diameter of the capsulotomy and the type of operation (phacoemulsification or extra-capsular extraction) had no apparent effect on ability of the capsules and zonules to stretch. Both the equation and the ratio indicate that the capsule does indeed have elasticity, namely 0.6 mm for every 1.0 mm of capsulotomy, or 60% elasticity. These findings have been reproduced by several other authors.[42,49]

Luck[42] and Morgan[49] compared the elastic properties of CCC versus diathermy capsulotomy which uses thermal energy to perforate the lens capsule. The findings show CCC to have an elasticity of 60% versus 36% elasticity for diathermy. Luck[42] postulates that the difference in elasticity between capsulotomy techniques is due to the microscopic anatomy of the capsular edge. The capsule is made up of a series of collagen lamellae that run parallel to the surface and at right angles to the zonular insertions. A tear in the capsule produced during CCC presumably runs in a curvilinear fashion along these natural fibrillar 'fault lines', and will obey vector forces induced by the surgeon when doing this. The lamellar arrangement of the capsule following CCC is illustrated in Fig. 15. Diathermy capsulotomy does not respect the natural arrangement of the collagen fibrils in the capsule. The irregularity of the capsulotomy margin and following diathermy capsulotomy is illustrated in Fig. 16.

[♣] The test is performed by using modified Vernier callipers with two pins firmly attached to the tips. The pins are placed in the capsulotomy and opened until the margin is torn.

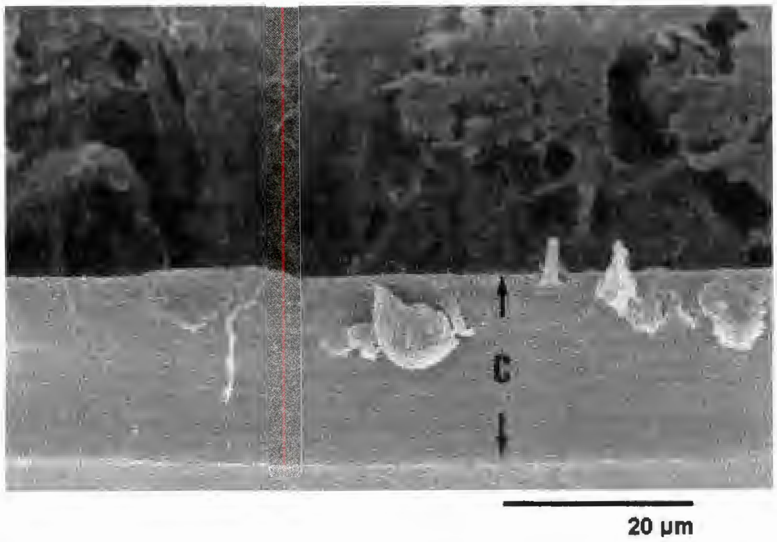


FIG. 15 SCANNING ELECTRON MICROGRAPH OF CAPSULAR EDGE (C) FOLLOWING CCC

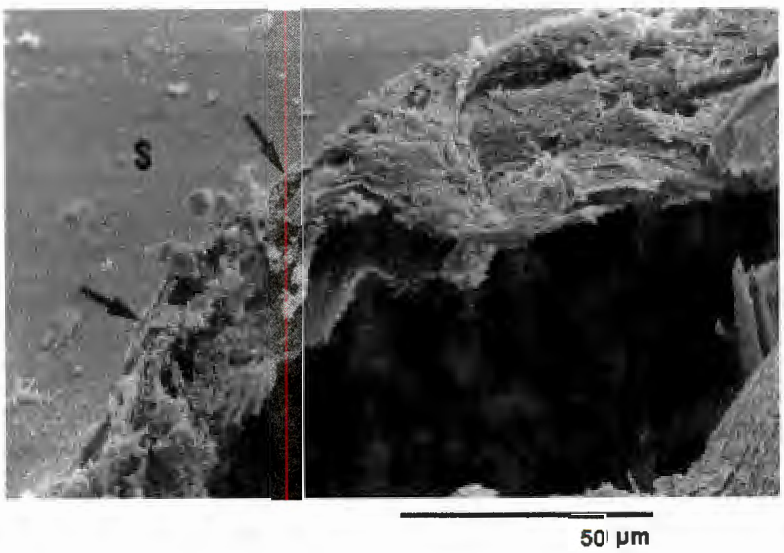


FIG. 16 SCANNING ELECTRON MICROGRAPH OF CAPSULAR EDGE (S) FOLLOWING DIATHERMY

1.4 PROBLEM STATEMENT AND OBJECTIVES

We are made to realise that much of the art of cataract surgery deals with the lens capsule. Combined with intact zonular structure, the lens capsule is the chief structure responsible for the continued stabilisation and support of the intra-ocular lens. Therefore, proper management of the lens capsule during cataract surgery is crucial to a successful result.

As of yet, the aim for a capsular opening that is smooth, continuous and ideally circular is practically impossible to achieve with current techniques. Present capsulotomy techniques are performed manually, take a long time to execute, are difficult to master, and run the risk of capsular tears. This contradicts a key objective in cataract surgery : to remove the cataract with minimal disturbance to the eye. This requires the surgeon to limit the number of manipulations necessary to accomplish surgery and to actively avoid random and superfluous movements.

There is a definite need for a method that is efficient, effective, easy to master and results in a well centred and smooth margined capsulotomy. In recent years it has been acclaimed that a capsulotomy produced by ultrasound could well overcome the difficulties experienced in performing capsulotomies.[7,47] Ayaki[7] claims to have performed an anterior 'phaco-capsulotomy' using the tip of the ordinary phacoemulsification handpiece. However, an investigation conducted by the author[26] showed the 'phaco-capsulotomy' was performed by direct manual pressure of the tip by the operator onto the anterior capsule rather than by the ultrasonic action of the phaco-tip as proposed by Ayaki.

This thesis proposes a new anterior capsulotomy technique using ultrasound to perforate the lens capsule during cataract surgery. The main objectives of this study are to:

1. Simulate the response of the human lens to ultrasonic frequencies,
2. Investigate methods to generate ultrasonic vibrations,
3. Experiment perforating the lens capsule using appropriate ultrasonic frequencies,
4. Consider the integrity of the capsular opening (i.e. its strength and elasticity),
5. Design an ultrasonic capsulotomy device that will compliment normal surgical procedures and produce a circular incision on the lens capsule,
6. Test and evaluate the ultrasonic device in its application,
7. Make recommendations were possible.

CHAPTER TWO

LITERATURE SURVEY

2.1 GENERAL HISTORY

There are many factors which, acting together, will determine whether ultrasound will perforate the lens capsule during anterior capsulotomy. Some of these factors are physical properties of the lens capsule, such as its modulus of elasticity. Other factors include the properties of the ultrasonic vibration, such as its frequency and power. This thesis will initially survey the clinical anatomy and mechanical parameters of the human lens and the lens capsule. Then, ultrasonic vibration and its effect on cells and membranes will be investigated.

2.2 ANATOMY AND PHYSIOLOGY OF THE HUMAN LENS

The internal anatomy of the human eye is shown in Fig. 17. The most distinctive feature of the eye is the lens which is located posterior to the iris. It is a transparent, biconvex, elliptical, semi-solid, avascular structure with smooth surfaces. Its anterior central region is exposed by the pupil and part of the iris glides over the anterior surface of the lens. The lens is supported by a system of zonules or suspensory ligaments that extend from the ciliary muscle to a 1.5 mm wide circular zone around the lens equator. The lens is almost entirely bathed by aqueous humor, a clear substance consisting of 98% water, a trace of sodium chloride and albumen.[55]

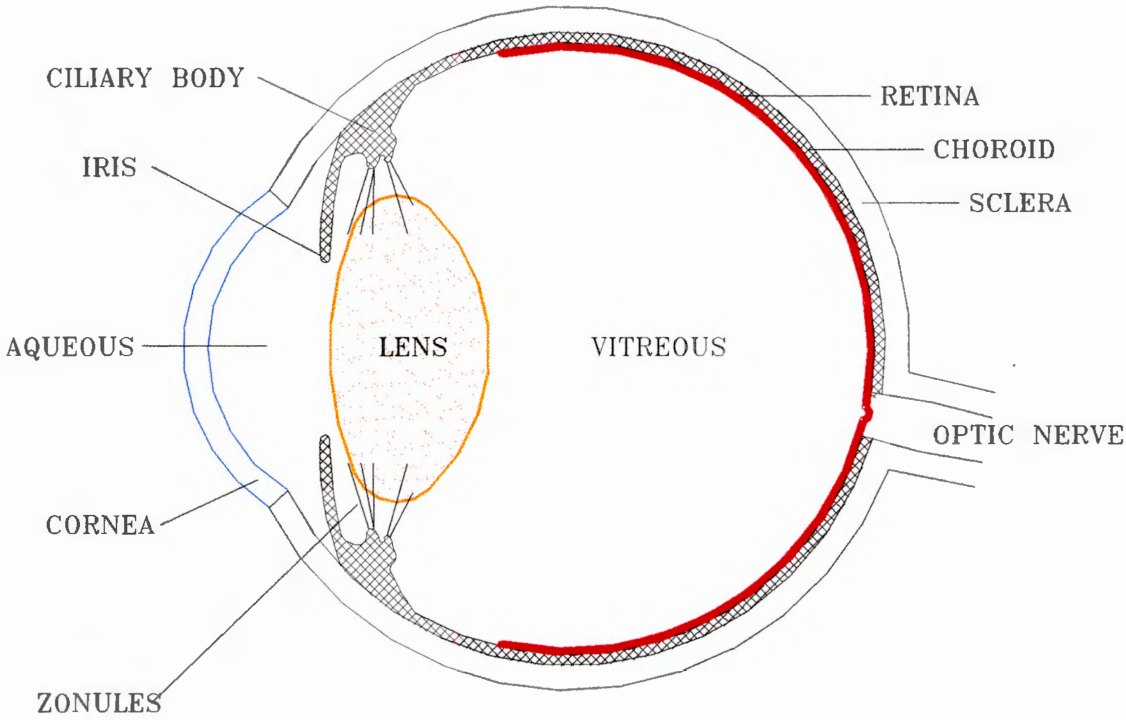


FIG. 17 DIAGRAMMATIC REPRESENTATION OF AN ADULT HUMAN EYE

The lens has been a subject of interest for centuries and the physical characteristics of the lens have been thoroughly investigated. (Table 1) However, little is known quantitatively of the biomechanical parameters of the lens except for a few certain facts. One of these is that the elastic properties of the lens originates mainly from the lens capsule. This is known through the works of Fisher[17] (1969) and more recently by Krag[34] (1997). It has been widely recognised that the elasticity of the lens allows accommodation of the eye, which is done by changing the shape of the lens. The constriction of the ciliary muscle causes reduction of tension in the zonules, thus enabling the lens to assume a more spherical shape in accordance with its elastic properties.

TAB. 1 MEASUREMENTS OF THE HUMAN LENS IN ADULT LIFE [55]

LENS	*Adults*	*Range*	*Units*
Equatorial diameter	9.5	9 to 10	mm
Axial thickness	5	maximum	mm
Radius of curvature			
Anterior	10	8 to 14	mm
Posterior	6	4.5 to 7.5	mm
Mass	266	maximum	mg
Volume	244	maximum	ml

The lens is a relatively simple tissue in the sense that it is made up of cells from only one cell lineage (e.g. blood, connective tissue or nerve cells are not present).[DU81] Although the lens proper is composed of a single cell type, discussions of lens structure are usually subdivided into the :

- lens capsule,
- epithelium,
- lens cells or fibres.

2.2.1 LENS CAPSULE

The lens capsule is an unusually thick basal lamina that surrounds the lens, forming the thickest basement membrane in the body. It is a transparent, homogenous and highly elastic envelope that is secreted in utero by the lens epithelium. The anterior capsule remains a basement membrane for the epithelial cells, while the posterior capsule is merely adherent to the fibre cells growing along its inner surface. As illustrated in Fig. 18, the capsule is thickest anteriorly especially at the region corresponding to the attachment of the suspensory ligaments. The thickness of the anterior capsule increases by twofold with age.[52]

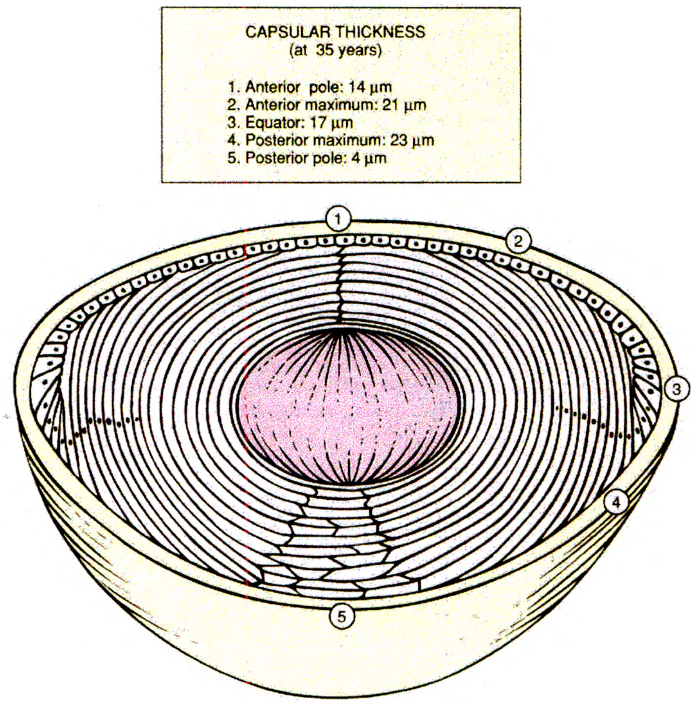


FIG. 18 CAPSULAR THICKNESS OF THE HUMAN LENS CAPSULE [29]

The elastic lens capsule contains the cortex and nucleus and allows the passage of nutrients into the lens as well as waste products out of the lens. Ultrastructurally, the lens capsule consists of extremely fine, filamentous, striated collagenous material. It is primarily composed of type IV collagen, although recent work by Luck[42] demonstrates the presence of type I and III collagen, making it unique among ocular basement membranes. The filaments are arranged in a lamellar fashion parallel to the surface of the capsule. The capsule contains no elastic fibres and its elasticity is attributed entirely to the superhelical constitution of the collagenous filaments as illustrated in Fig. 19.

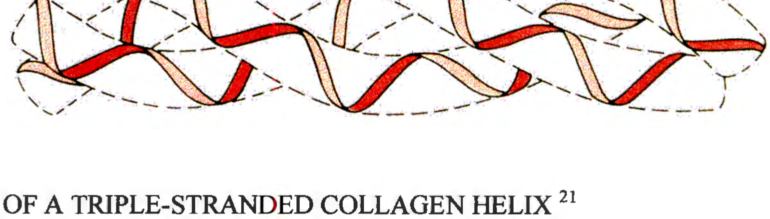


FIG. 19 MODEL OF A TRIPLE-STRANDED COLLAGEN HELIX [21]

The amount of energy required to stretch the lens capsule to the point of rupture is about four times as great as that required to stretch an 'ideal rubber' by the same amount.[19] This is because rubber, unlike collagen in the lens capsule, is a network of non-extensile randomly arranged long-chain molecules. Initially they are in a bundle but a tensile stress straightens them out to a point where one is pulling on the stiff primary chemical bonds in the backbone of the chain. The result is an *S*-shaped stress-strain curve. The lens capsule, however, is composed of collagen filaments coiled to form superhelices which are able to pass from a helical to a non-helical (or extended) state before rupture. This results in a characteristic *J*-shaped stress-strain curve. The comparison of typical stress-strain curves of a capsular basement membrane and of a rubber of similar thickness is depicted in Fig. 20.

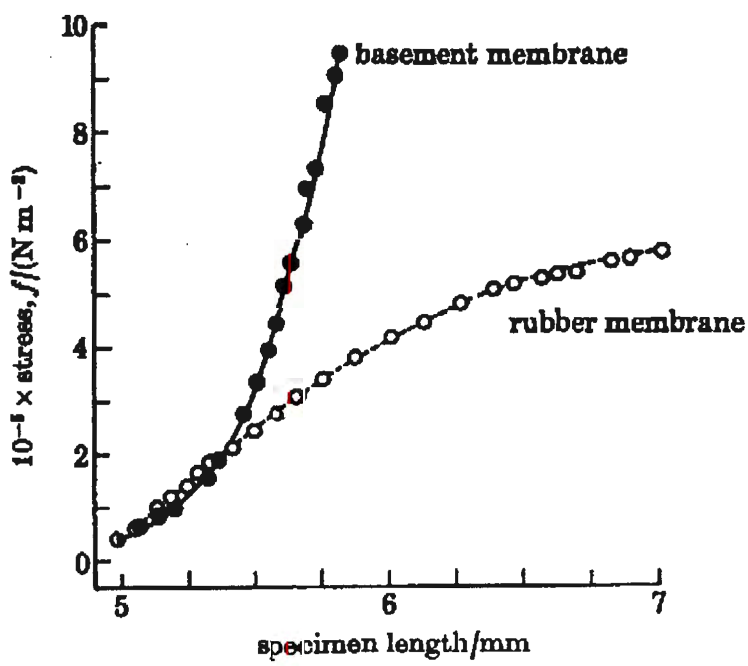


FIG. 20 STRESS - STRAIN CURVES OF THE LENS CAPSULE (BASEMENT MEMBRANE) AND A RUBBER MEMBRANE OF THE SAME THICKNESS [19]

As the function of an organ changes in a lifetime, so does the mechanical properties of its tissue. Ageing of the human anterior lens capsule seems to be associated with a progressive loss of mechanical strength due to compositional changes of the tissue. Present data by Krag[34] shows that the ultimate tensile strength decreases by a factor of five during a life span, and the extensibility decreases by a factor of two. These biomechanical properties of the lens capsule play an important role in cataract surgery. The capsule's toughness indicates how easily the capsule is torn. The extensibility and stiffness of the capsule has surgical implications in relation to nucleus expression in extra-capsular surgery. The maximum strength of the capsule is of importance in relation to surgical manipulations of the lens capsule during nuclear extraction.

Few other investigations have been carried out to describe quantitatively the mechanical properties of the human lens capsule. Fisher[17] studied the elastic properties of the human lens capsule but it included several approximations, problems with clamping the tissue and this may have led to an underestimation of extensibility and ultimate tensile strength. Also, Fisher described the elastic behaviour of the lens capsule as linear, but recent studies by Krag[34] show increasing evidence that the lens capsule exhibits non-linear elastic behaviour (i.e. the elastic stiffness varies exponentially with strain). This non-linear behaviour is clearly depicted in Fig. 21.

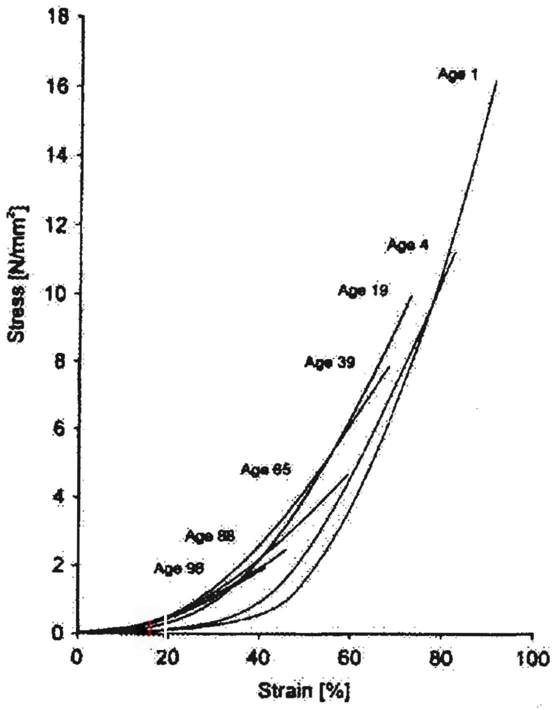


FIG. 21 STRESS-STRAIN CURVES OF THE HUMAN LENS CAPSULE FOR DIFFERENT AGES[34]

The mechanical properties of the lens capsule obtained by Krag[34] are recorded in Table 2. The stress values are calculated as conventional engineering stresses since the change in cross section of the capsule was not measured as it was tensioned. True stresses are then calculated with the assumption that the capsule is incompressible (Poisson's ratio = 0.5) and therefore the cross sectional area reduces by a factor equal to the extension ratio. Krag[34] may, however, be incorrect in adopting isovolumetric calculations when dealing with soft tissues at high extensions.

TAB. 2 ELASTIC PROPERTIES OF THE HUMAN LENS CAPSULE [34]

LENS CAPSULE	*10 years*	*60 years*	*Range*	*Units*
Tangent modulus	30	15	44.8 to 4.4	N/mm^2
Young's modulus	6	3		N/mm^2
Ultimate stress	12	6	17.5 to 1.5	N/mm^2
True ultimate stress			31.8 to 2.1	N/mm^2
Extensibility	91	66	108 to 40	%

2.2.2 LENS EPITHELIUM

The epithelium is a single layer of cuboidal cells situated beneath the capsule and confined to the anterior and equatorial aspect of the lens. The equatorial epithelial cells retain their mitotic activity throughout life to give rise to secondary lens cells or fibres. The older cells are retained and pushed towards the centre, thus accounting for the progressive growth and central densification of the lens with age. Measurements of cell density of human lens epithelium range from 3,900 to 5,780 cells/mm^2.[29]

2.2.3 LENS FIBRES

The lens cells, with their highly organised concentric shells, resemble fibres and make up the bulk of the lens. All post-embryonic lens fibres are derived from equatorial epithelial cells. The oldest cells are contained within the core or nucleus of the lens and throughout life new cells are added superficially in a series of concentric layers. As the cells become older and more imbedded within the lens they undergo several changes, they lose organelles, to some extent they lose structural integrity and they become progressively more metabolic inert.

The dimensions and cross sectional profiles vary according to the location and the age at which the fibre was synthesised. The lens constitutes 2400 lamellae made up of individual fibres.[55] Mature lens fibres are six-sided ribbon shaped and extend from the anterior to the posterior pole. These fibres are illustrated in Fig. 22.

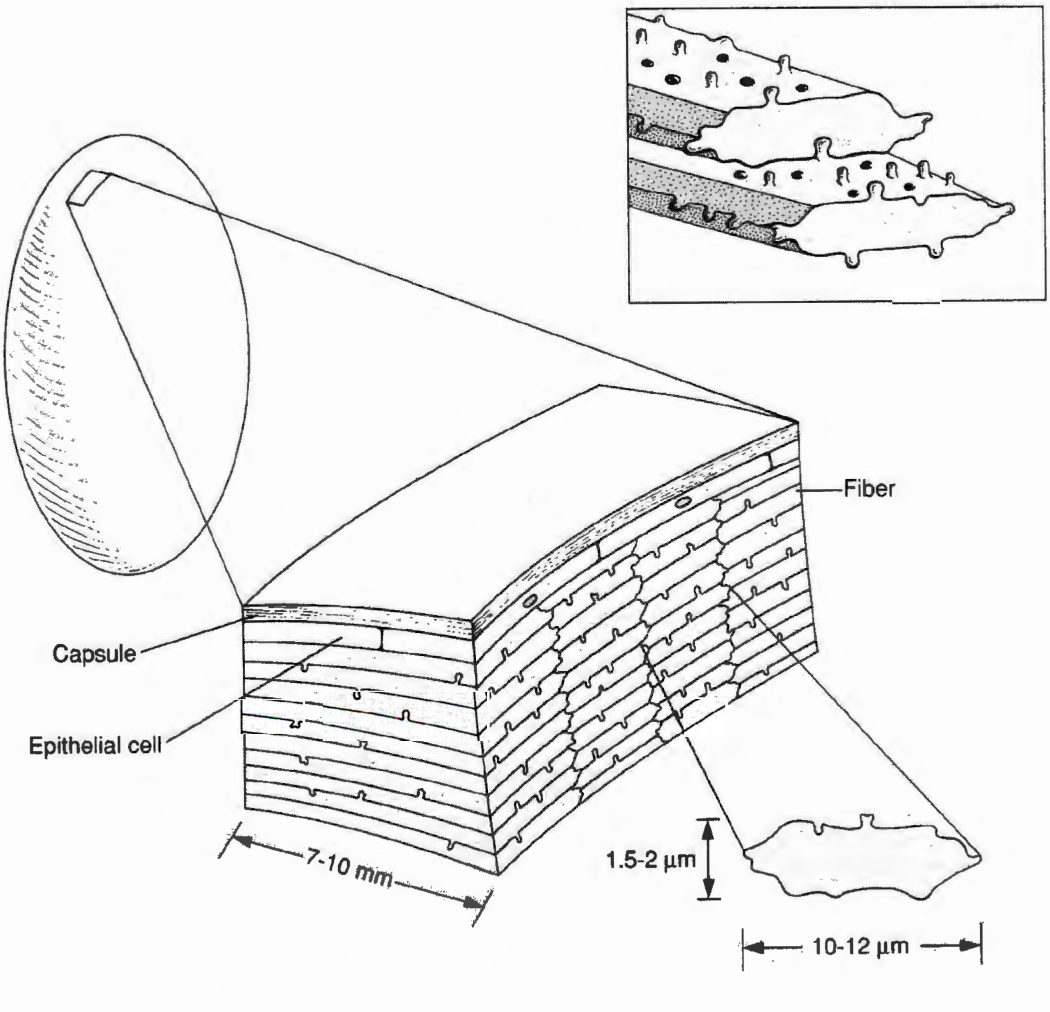


FIG. 22 CROSS SECTION THROUGH ANTERIOR PART OF THE LENS [29]

Table 3 and Appendix A.1 indicates that the Young's modulus of the human lens varies with age. Fisher[18] observed that both very young and very old lenses have linear isotropic elastic properties but that in between these extremes, Young's modulus depends on the direction in which it is measured. This is due to the variations in the elasticity observed in the cortex and the nucleus of the lens, the cortex having a higher isotropic elasticity than that of the nucleus.

TAB. 3 ELASTIC PROPERTIES OF HUMAN LENS FIBRES [18]

LENS FIBRES	*Birth*	*60 years*	*Units*
Poisson's ratio	0.49		
Young's modulus			
Polar	750	3 000	N/m^2
Equatorial	850	3 000	N/m^2

2.3 ULTRASOUND

Vibration is a phenomenon which touches every branch of science. At high frequencies, above 18 000 cps, the waves set up by vibrations are inaudible and are described as *ultrasonic*. Ultrasonic waves have some remarkable properties, one of them being that they can transmit much more power from one point to another than ordinary sound waves can. That is because unlike sound waves, ultrasonic waves are able to "penetrate" by the ability to concentrate the waves into beams. This ability increases as the frequency increases. In fact, ultrasonic waves obey all the familiar laws of wave motion and are subjected to reflection, refraction, dispersion, interference, diffraction.

The purpose of this section is to discuss ultrasonic vibrations as an occurrence engineers have to contend with. Ultrasonic vibrations aren't always the troublesome by-product of engineering practice. On the contrary, it is often useful and essential in industry (e.g. mechanical shakers) and medicine (e.g. dentistry). The following diagram of Fig. 23 illustrates how mechanical vibration can diffuse into a variety of medical applications.

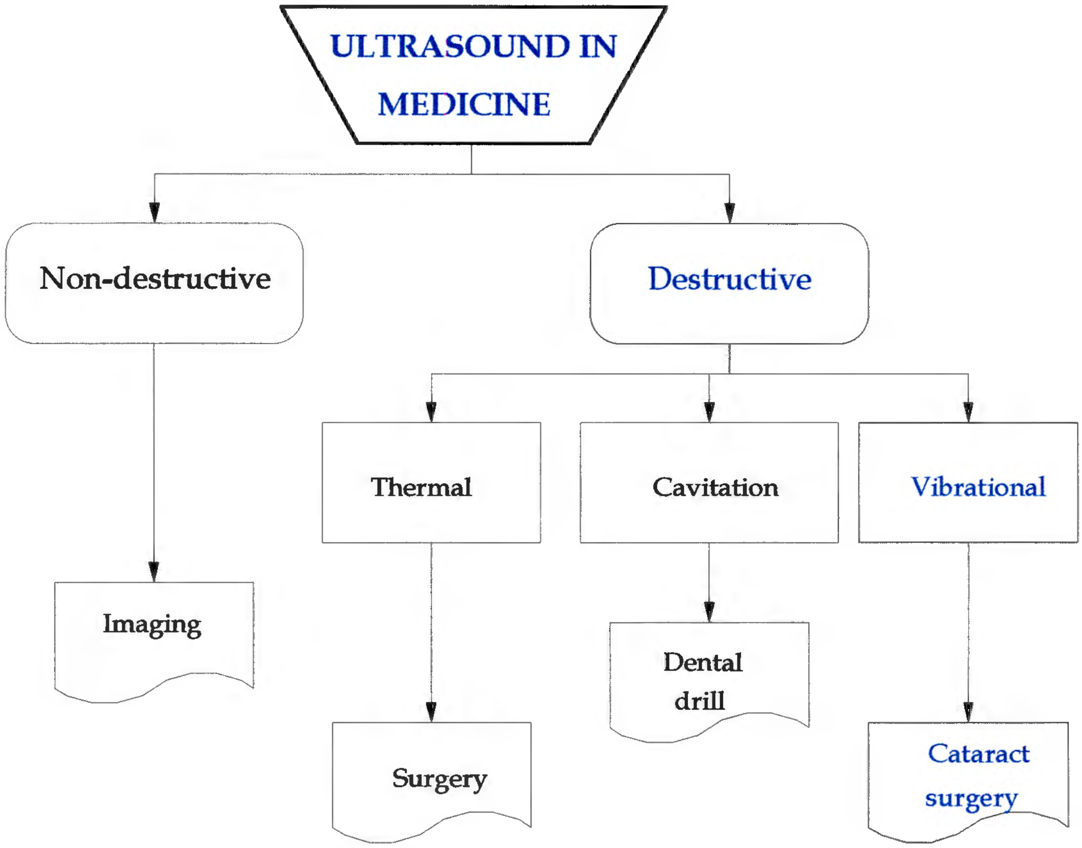


FIG. 23 ULTRASOUND APPLICATION IN THE MEDICAL FIELD

2.3.1 ULTRASOUND GENERATORS

There are many methods employed to generate ultrasound but most applications of ultrasound make use of solid generators. They function by cyclically changing their dimensions. There are two classes of materials that exhibit this phenomenon:

1. Magnetic materials which change their shape due to *magnetostriction*.
2. Single crystals which are made to expand and constrict due to the *piezoelectric* effect.

Magnetostrictive Transducers

Magnetostrictive transducers can be used to convert electrical energy to mechanical energy and vice versa. These transducers are based on packs of ferromagnetic lamellae that are able to generate an alternating magnetic force within a hollow coil of wire (a solenoid) when an alternating electric current is passed through that wire. The core placed within the solenoid changes its length with the same frequency. The core is chosen to be resonant length (half a wavelength) for maximum displacement.

The advantages of magnetostrictive transducers include contact free excitation, thus avoiding deterioration between the electric junction and the transducer. Also, the transducers and the coupling elements are rugged therefore withstanding mechanical damage. The primary disadvantage, however, is a low grade of efficiency. Only a small part of the energy input is transformed into mechanical action, the majority energy becoming heat. Heating not only carries the risk of tissue burn but also makes the transducer lose efficiency with rising temperatures. Therefore, magnetostrictive transducers need a separate cooling system.

Magnetostrictive transducers are best applied to low frequency applications in the frequency range of 5 to 40 kHz.[10]

Piezoelectric Transducers

Ultrasonic power is most often produced by an enclosed piezoelectric crystal that converts electricity into mechanical vibration. If the piezoelectric crystal is placed in an alternating electric field, then longitudinal oscillations will occur in the surrounding medium due to expansion and contraction of the crystal. The actual amplitude of the crystal is directly proportional to the applied voltage and the amplitude will be at a maximum when the crystal is excited at its resonant frequency.

The advantages of piezoelectric crystals include a high grade of efficiency and therefore very little inherent heat generation, with no need for extra cooling. Disadvantages include the structural brittleness of the crystal itself, and the connection points between the multiple layers of crystals that are needed to provide adequate stroke amplitudes. These properties limit the longevity of such transducer. They deteriorate both by accidental mechanical damage and by the oscillation they produce.[52]

Piezoelectric crystals can be used conveniently at frequencies up to 2 MHz.[10]

2.3.2 ULTRASONIC TRANSDUCER SYSTEMS

For many applications of ultrasound, large vibrational amplitudes are required. With a piezoelectric crystal one finds high forces at small amplitudes and it is therefore necessary to electronically and mechanically intensify the motion of the ultrasound vibrations without altering the frequency. This can be achieved by (1) amplifying the power into the crystal and (2) attaching a concentrator onto the transducer. The use of transducer systems with concentrators is now a standard practice in many applications of ultrasonics. Such a system consists of three components: *transducer*, *concentrator* and *backing*. The construction of a piezoelectric transducer system is illustrated in Fig. 24.

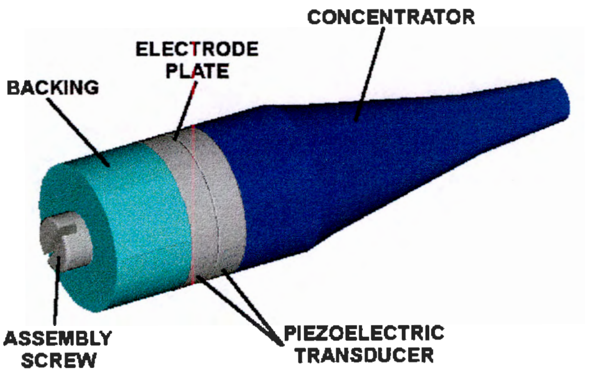


FIG. 24 COMPONENTS OF A PIEZOELECTRIC TRANSDUCER SYSTEM

The vibration is created by two piezoelectric plates sandwiched together. When an alternating current is supplied to the ceramics, the top and bottom ceramics begin to dilate and constrict in opposite directions, thereby generating piston vibrations down the concentrator. The transducer executes longitudinal vibrations which is then communicated to the concentrator, whose function is to increase the vibrational amplitude at the tip. As illustrated in Fig. 25, the acoustic energy in the concentrator becomes concentrated on smaller and smaller areas while both the amplitude and particle velocity increase. For an effective transmission without energy losses all the parts of this compound oscillating system need to be in perfect resonance.

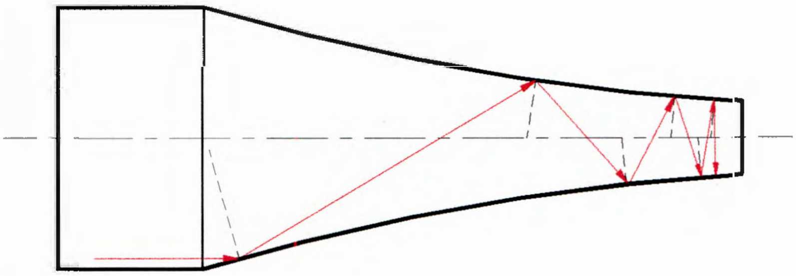


FIG. 25 PROPAGATION OF SONIC ENERGY IN AN EXPONENTIAL CONCENTRATOR [43]

The concentrator also acts as a coupling agent between the transducer and the surface on which it is applied, encouraging contact between the surfaces for the transmission of acoustic energy. Concentrators obtain high ultrasonic intensities at its end point without excessive power input to the transducer. Generally, the concentrator length is either one half wavelength or one full wavelength. These are half-wave rods that are tapered rather than of a uniform diameter. Any type of tapering will increase the amplitude of motion. Several types of tapering common in industrial equipment are:

- exponential
- conical
- cylindrical quarter-wave step

The magnitude of stress levels (σ) and the longitudinal displacement (d) for each type of concentrator is illustrated in Fig. 26. Cylindrical quarter-wave step concentrators give the highest amplification factor. They are also easy to manufacture as they effectively consist of two cylinders, each a quarter wavelength long. These are normally produced out of a single block with a large radius of curvature at the change of diameter to reduce the risk of fatigue fracture.

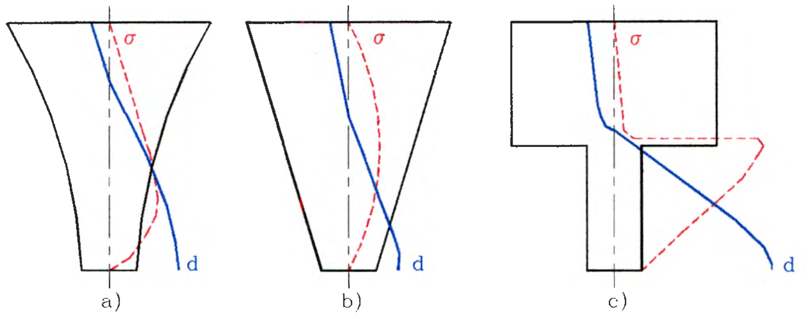


FIG. 26 CONCENTRATOR DESIGNS : A) EXPONENTIAL B) CONICAL C) STEP CYLINDER [43]

2.3.3 PHYSICAL CHARACTERISTICS

Ultrasonic action produced by ultrasound transducer systems is combination of three variables:

1. amplitude
2. frequency
3. coupling force

The *amplitude* of the vibration determines how far the concentrator tip will penetrate into the applied body with each oscillation. The *frequency* determines how much of the amplitude will be transformed productively into penetration and how much will be transferred unproductively into the displacement of the body. This depends on the mass, and thereby the inertia, of the fragment engaged. The *coupling force* is crucial in transmitting the vibratory force into the body. Coupling between the concentrator tip and the applied body can be obtained by pressing the tip against it. In the case of the human lens, the zonules provide the counter-coupling force.

2.3.4 RESONANCE

Every piece of material has an inherent frequency at which it vibrates naturally, called its resonant frequency. This 'free vibration' of a system defines a kind of a personality and this is what determines the system's behaviour under a variety of conditions. If a pulsating excitation is applied at a natural frequency, then a violent motion may be expected. This magnification of the motion is known as *resonance*. If excited to vibrate at this frequency, the transformation into vibratory amplitude is optimal and the transformation into other forms of energy, largely heat, is minimised.

Every material has several resonant frequencies. A string can be shown to possess a series of shapes of vibration, each with an associated frequency as shown in Fig. 27. The shapes are known as *modes* and each mode is associated with a rate of decay of motion, as well as with a frequency.

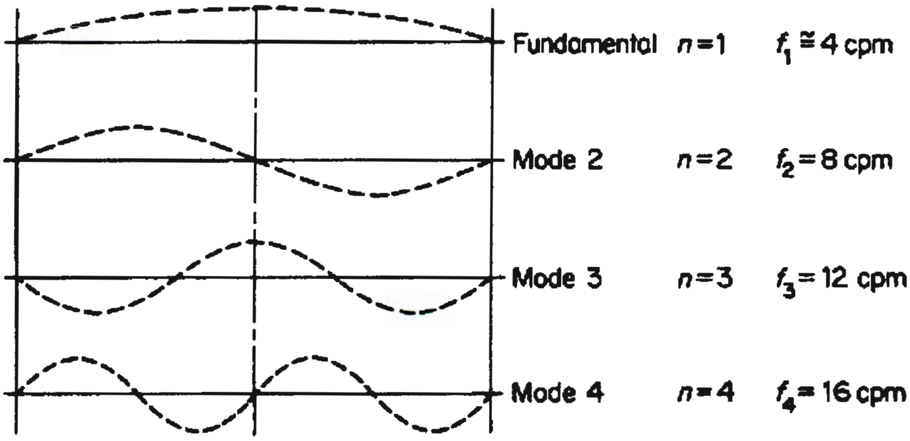


FIG. 27 MODE SHAPES OF A STRING [54]

2.4 BIOPHYSICAL MECHANISMS OF ULTRASONIC VIBRATORS

Research claims that ultrasound can change the morphology of cells and membranes. The morphological change includes cell destruction via:

- direct impact
- cavitation
- shock waves
- thermal increase

Although the biological effect of vibration dependsupon its intensity and duration, by far the most significant characteristic of the vibration is its frequency. Only in the frequency range of ultrasonics is the body affected at a cellular level, as illustrated in Fig. 28.

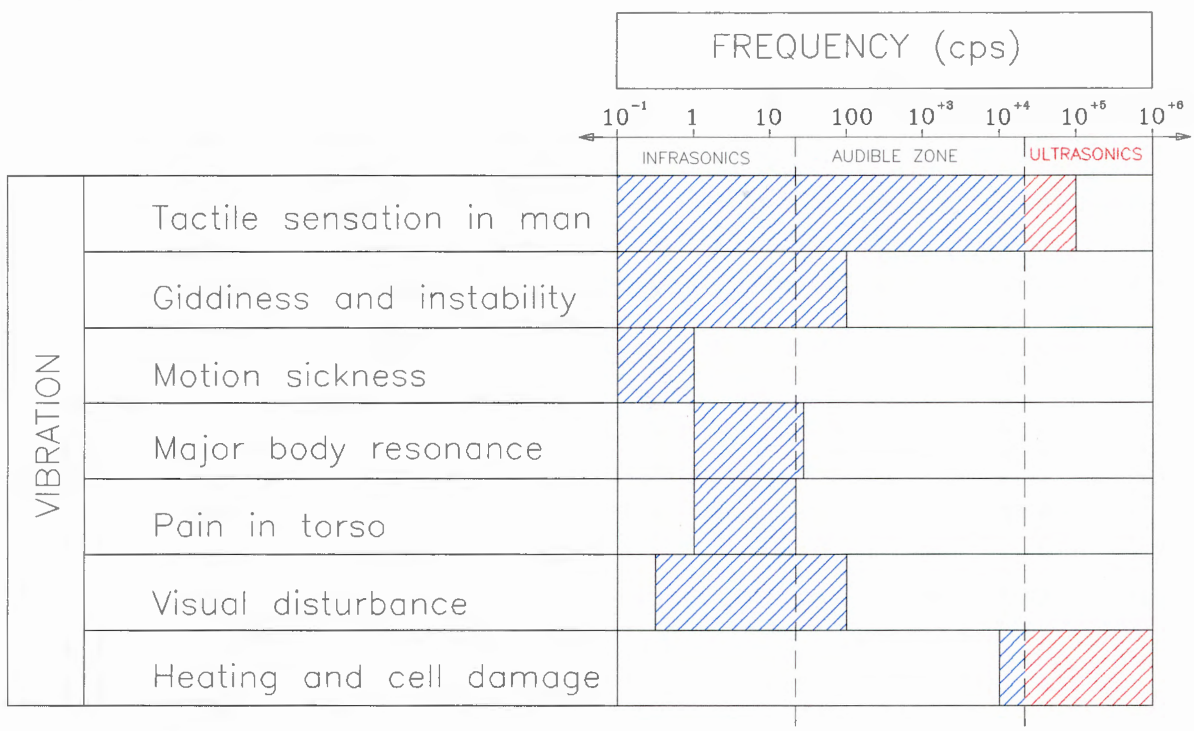


FIG. 28 TABLE OF FREQUENCY EFFECTS ON THE HUMAN BODY [8]

2.4.1 DIRECT IMPACT

Direct impact acts much like a jackhammer. The efficiency of this mechanism (effective penetration of the tip into the body and its destruction) depends on two main prerequisites:

1. Force coupling by close mechanical contact between the tip and the membrane. This can be achieved by pressing the ultrasonic tip against the lens capsule.

2. High forward acceleration of the ultrasound tip. The high acceleration breaks the frictional bonds within a membrane.

Ultrasonic vibration imposes mechanical forces onto the tissue in contact. The molecules in the medium are made to oscillate, but beacuse of high attenuation (absorption of ultrasound intensity), adjacent portions of the membrane are either still or vibrating at a smaller amplitude. It is at this point that the membrane may rupture by fatigue.

2.4.2 CAVITATION

Cavitation, the formation of a bubble or cavity in liquids, is another useful form of energy generated by ultrasound. Although some surgeons think of cavitation as producing annoying air bubbles, it offers some advantages.

Cavitation is the phenomenon that occurs when a solid body moves against a liquid at high speed. In phacoemulsification, this occurs all around the phaco-tip. In the border layers, the rapid movement creates micron-sized bubbles of almost pure vacuum. They last only for microseconds and are “imploded” by the surrounding fluid that fills them up. (Fig. 29) This implosion causes an unusual environment. The heat generated is extraordinary, but the region is so small that the heat dissipates quickly. In addition, the implosion creates a tremendous negative pressure. The filling up of these cavitation bubbles occurs by a thin and extremely fast jet of water that results from the high pressure gradient between surrounding fluid and vacuum in the bubble. This water jet is highly destructive. Cavitation destroys everything at the border at which it occurs and results in ultra fine emulsification of the lens particles.

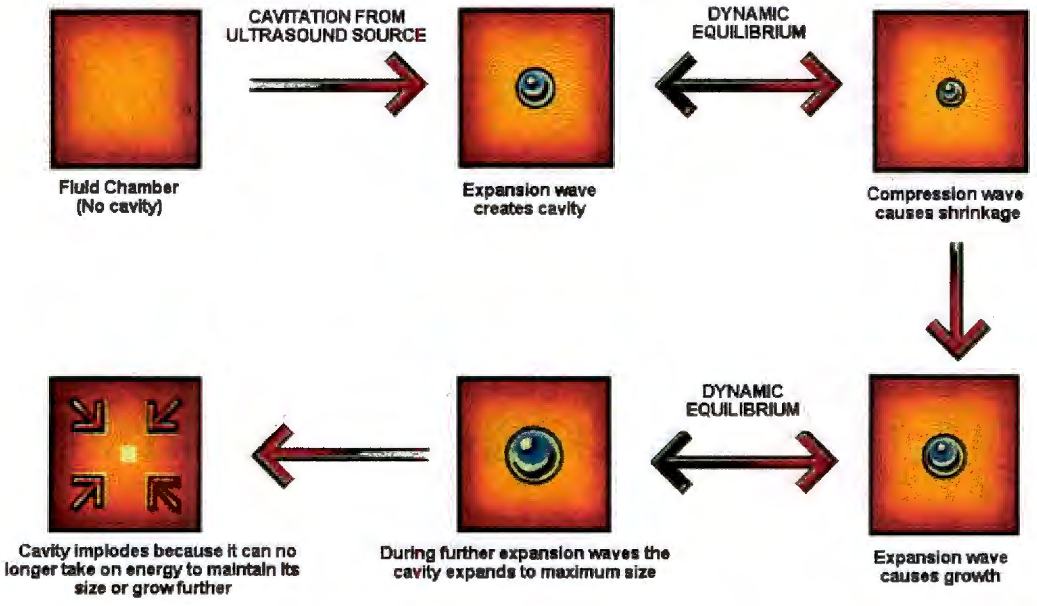


FIG. 29 LIFE CYCLE OF A BUBBLE IN A FLUID EXPOSED TO ULTRASOUND [51]

2.4.3 SHOCK WAVES

Shock waves are pressure waves created by an oscillating surface that spread into the surrounding medium at the speed of sound in that medium. The inherent mechanical force of the shock wave determines its destructive potential. Because it normally radiates in a spherical pattern from its source surface as seen in Fig. 30, the shock wave is rapidly dissipated. The wave is additionally dampened by the inertia of the medium. Therfeofroe, shock wave energy and mechanical destructive power are both proportional to the surface area that is oscillating and the amplitude of the oscillation.

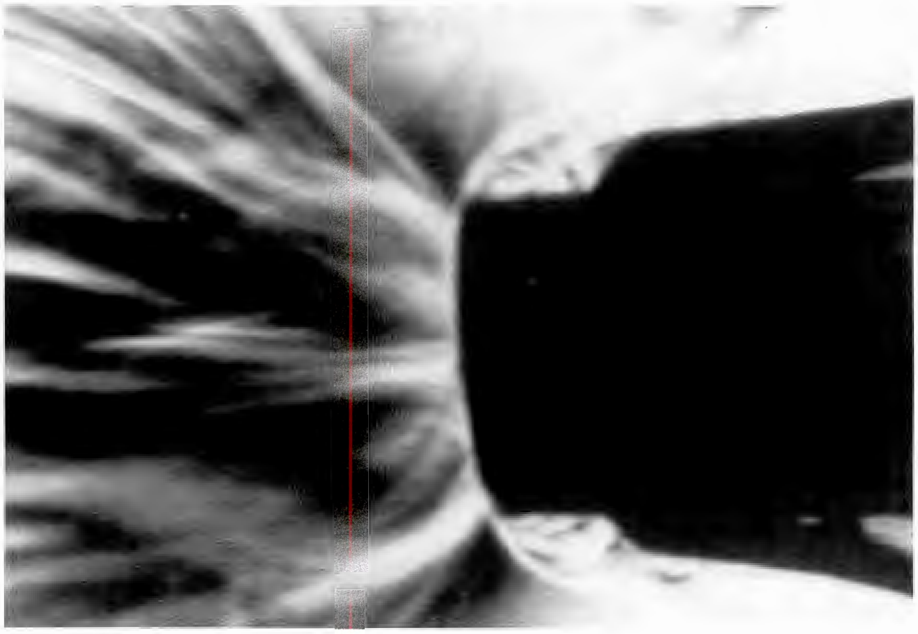


FIG. 30 CIRCULAR TURBULENCE AT THE PHACO-TIP OF DIAMETER 2.5 mm [31]

2.4.4 THERMAL EFFECT

Heat will always be created when one form of energy is transformed into another. Some heat is generated by the conversion of electrical energy into mechanical energy. Another source of heat comes from cavitation between the vibrating tip and anything directly in contact with it. This heat is transmitted to the surrounding tissue by direct contact. The amount of heat present in the tissue is dependant on its absorption characteristic and the amount of ultrasonic energy it is exposed to. Collagen, the main constituent of the lens capsule, shrinks to about one-third of its initial length at 65°C.[22] The shrinkage is due to a breakdown of the crystalline structure and it becomes rubbery, with a Young's modulus of about 1 MPa.

CHAPTER THREE

METHODOLOGY OF THE DESIGN

3.1 DESIGN RATIONALE

The literature review has established the need for an improved and safer technique to create an opening on the anterior lens capsule. The use of ultrasound to execute a capsulotomy although considered, has not yet been developed. This chapter outlines the design process of an ultrasonic device that could perform capsulotomy in cataract surgery.

3.1.1 PROBLEM STATEMENT

Capsulotomy is a critical procedure in cataract surgery. Since the introduction of continuous curvilinear capsulorhexis (CCC) using a cystotome, the quality of cataract surgery has improved dramatically. However, this technique is highly susceptible to complications such as the high incidence of radial tears on the capsule mainly due to the difficulty in mastering the CCC technique.

There is a need in cataract surgery for instrumentation that performs a controlled, predictable and smooth-edged capsulotomy. The use of ultrasound to perforate the anterior surface of the lens capsule would be a viable alternative to current capsulotomy techniques, but only if it proves to be simple and effective.

3.1.2 REQUIREMENTS

The design must fulfil the following requirements :

- use ultrasound to perforate the lens capsule
- compliment small incision surgical procedures
- be simple to perform
- produce a standard capsulotomy of about 5 mm diameter
- result in an incision with a low incidence of tears in order to withstand stretching during nucleus expression or phaco-emulsification

3.1.3 CONSTRAINTS

The instrument must satisfy the following constraints :

- produce a centred incision on the capsule
- <u>not</u> damage non-target tissues such as the cornea or the iris
- enter the eye from a 3.2 mm wide incision in the sclera
- be manufactured from medical grade stainless steel or titanium
- withstand sterilisation

3.1.4 CRITERIA

The following criteria are desirable for the instrument :

- have an aesthetic appearance
- allow for operator's comfort (be user-friendly)
- be reliable in reproducing the incision

3.2 DESIGN DEVELOPMENT

It is a design requirement that the ultrasonic instrument comply with small incision cataract operating procedures. In modern cataract surgery, a 3.2 mm incision is created in the sclera of the eye through which capsulorhexis and phacoemulsification is performed. Prior to inserting the IOL implant, this incision is subsequently enlarged to 5 mm.♦ It is a design constraint to perform a 5 mm diameter capsulotomy on the anterior surface of the lens through a 3.2 mm scleral incision. This amongst other anatomical constraints are illustrated in Fig. 31.

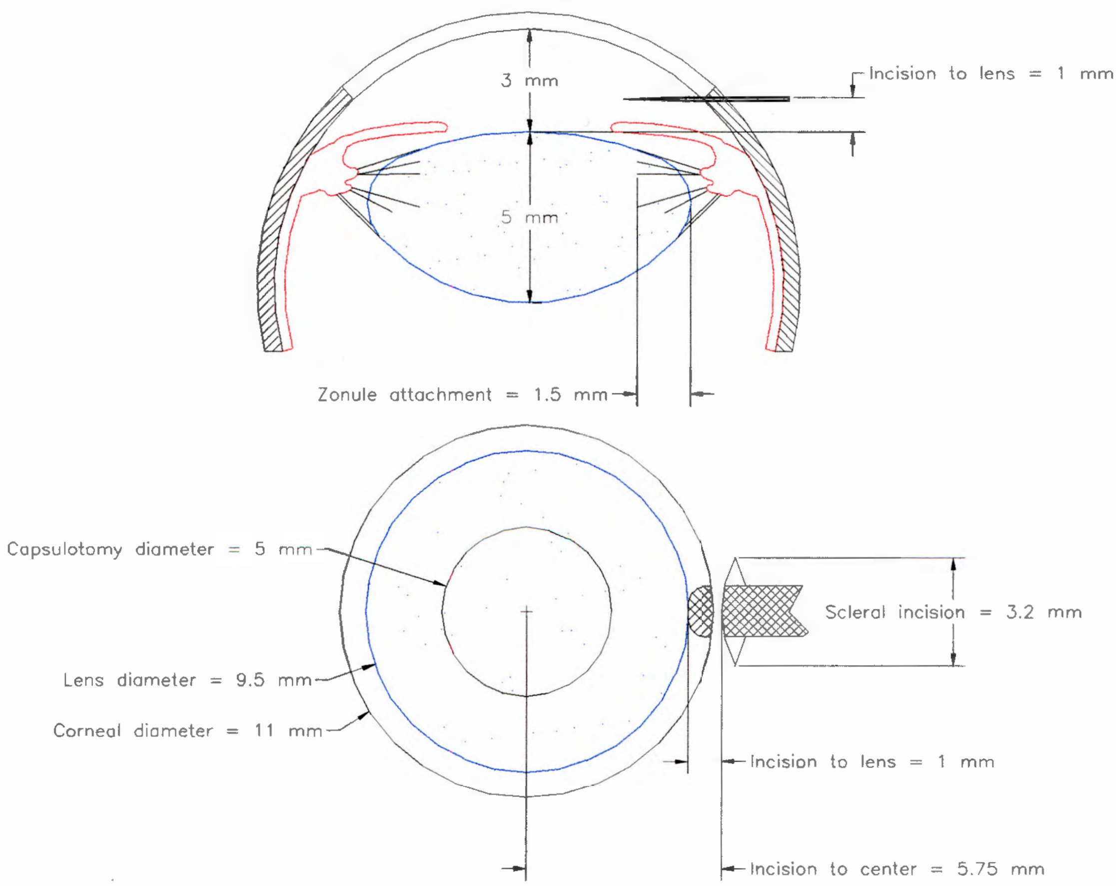


FIG. 31 ANATOMICAL AND SURGICAL DESIGN CONSTRAINTS

♦ Small incision surgery is popular because it reduces post-operative complications such as astigmatism which results from the flattening of the cornea due to the incision.

3.2.1 CONCEPTUAL DESIGN

During the initial stages of the conceptual design development, three main concepts were considered :

1. the instrument tip ~ output
2. the instrument stem ~ transmission
3. the ultrasonic transducer system ~ input

INSTRUMENT TIP

Fundamental to the success of the capsulotomy is the way in which the instrument tip performs the perforation on the capsule. The tip is designed to :

- enter the eye through a 3.2 mm scleral incision
- perform a capsulotomy of about 5 mm diameter which is an optimal size for nucleus extraction
- allow for force coupling between the tool and the lens capsule
- be rigid and strong enough to transmit ultrasonic vibrations without inducing flexural-mode (bending) vibrations
- be light to minimise the load on the ultrasonic transducer

The proposed design of the instrument tip is illustrated in Fig. 32. The tip is oval shaped and has a length of 5 mm and a width of 3 mm to allow entry through the scleral incision. The cutting surface of the tip is ground down to a concave shape (10 mm radius of curvature) to enable force coupling between the ultrasonic tip and the convex lens capsule. The weight of the tip is reduced by inserting two holes of 1 mm diameter into the tip.

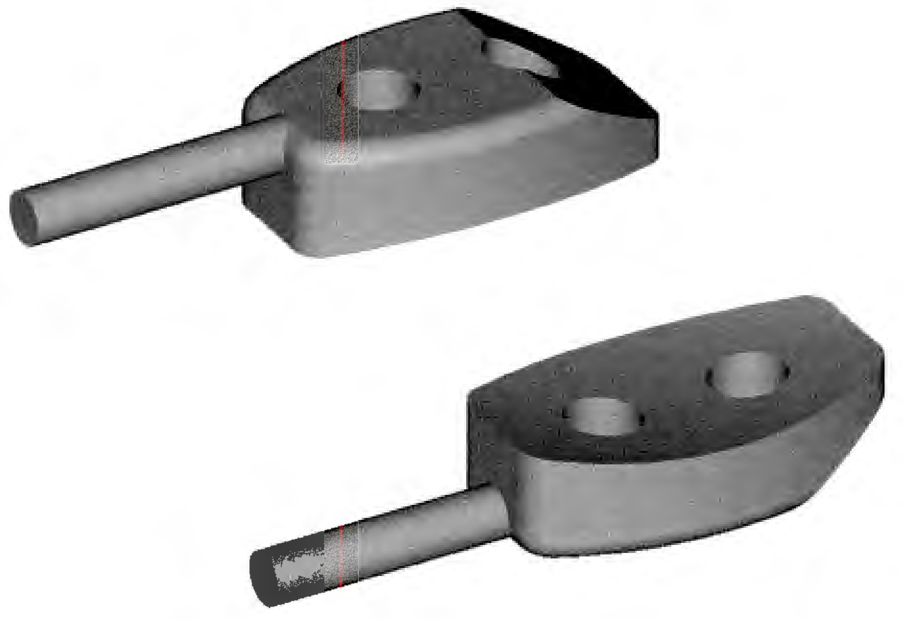


FIG. 32 PROPOSED DESIGN OF THE INSTRUMENT TIP

Since it is a design requirement to create a capsulotomy of 5 mm diameter in size, two perforations are made on the lens capsule with the oval tip. By overlapping the two perforations by 1 mm, a nearly circular perforation is created with two triangular flaps pointing centrally. The triangular flaps are areas of low stress concentration and they do not disturb the integrity of the cellular arrangement around the capsulotomy, as illustrated in Fig. 33.

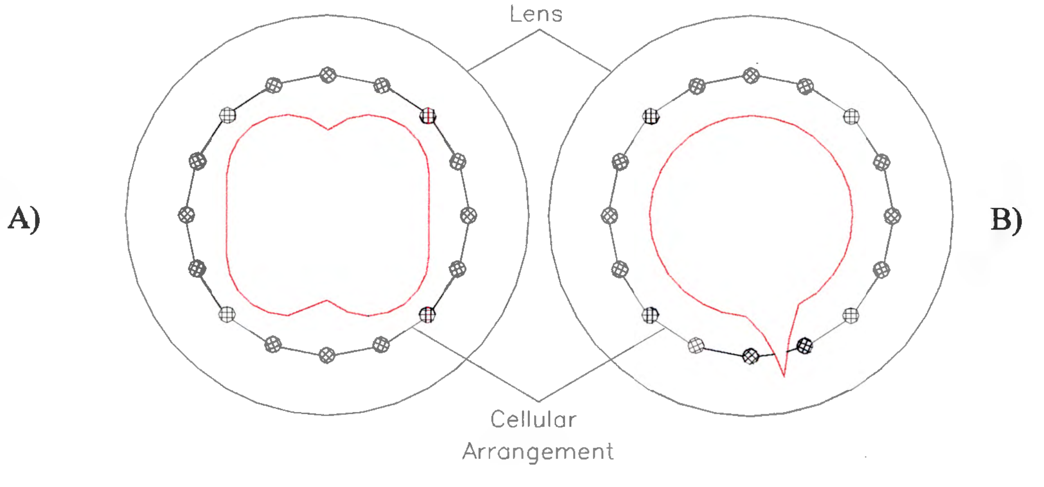


FIG. 33 INTEGRITY OF CELLULAR ARRANGEMENT IS RETAINED BY THE PROPOSED CAPSULOTOMY (A) AND IS DISTURBED BY A RADIAL TEAR (B)

INSTRUMENT STEM

The function of the stem is to support the tip and transmit vibrations from the ultrasonic generator to the tip. The design limitations require the stem to :

- permit lateral movement in the 3.2 mm scleral incision to allow for two perforations to be made on the lens capsule
- avoid contact of non-target tissues, such as the iris or the cornea

The stem is designed as a cylindrical rod with a main diameter of 2.5 mm which steps down to 0.7 mm. The smaller diameter facilitates lateral movement in the 3.2 mm scleral incision for the offset perforations. It also offers enough clearance from the cutting surface of the tip to avoid contact with the iris. Also, the stem is enveloped in a silicone sleeve which offers added protection to the sclera. A section view of the proposed silicon sleeve is illustrated in Fig. 34.

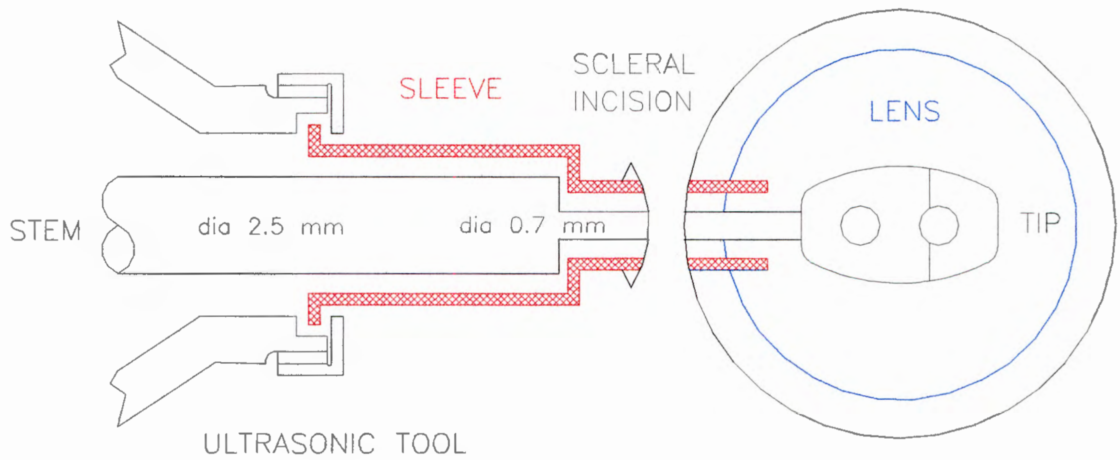


FIG. 34 SCHEMATIC DRAWING OF THE INSTRUMENT STEM WITH SLEEVE

ULTRASONIC TRANSDUCER SYSTEM

Ultrasound can be generated by either magnetostrictive or piezoelectric transducers. Current application of ultrasound in cataract surgery uses a magnetostrictive transducer to drive the phacoemulsification tool at a frequency of 40 kHz. Although this tool is effective in emulsifying the lens nucleus, attempts made by the author[26] disproved the well spread belief by ophthalmic surgeons[7,47] that the phaco-tool can perforate the anterior lens capsule ultrasonically. Ultrasonic transducer systems operating at higher frequencies than 40 kHz are commonly designed using piezoelectric crystals.

A schematic drawing of the transducer design powered by a piezoelectric stack is shown in Fig. 35. Of various designs discussed in Appendix C, this was considered to be the most feasible. It places the least load onto the crystal, thereby maximising the power, amplitude and acceleration♠ transmitted to the ultrasonic tip. The design consists of two sandwiched piezoelectric crystals generating longitudinal vibrations, a concentrator and a backing. The transducer system is attached to the hand-piece by two sets of O-rings which are located at nodal points of vibration along the transducer system.

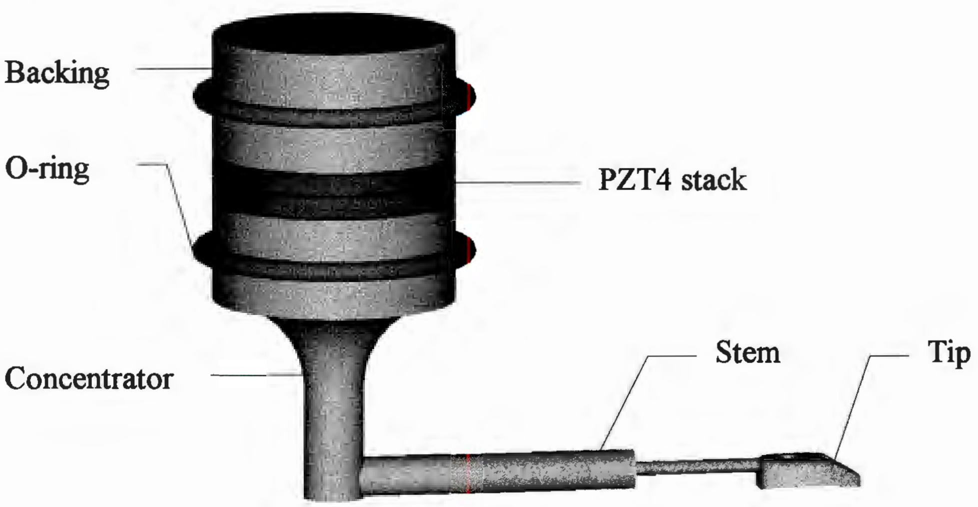


FIG. 35 PROPOSED DESIGN OF THE ULTRASONIC TRANSDUCER SYSTEM

♠ Acceleration is the key concept in membrane perforation. Quick acceleration of the tip will not allow the membrane to move with it and perforate the membrane by "cutting" through the cellular bonds.

3.2.2 CHOICE OF MATERIALS

The choice of materials in medical applications is critical. Titanium exhibits small structural losses and fragmentation during high frequency. Presence of metallic fragments that occur with more brittle materials than titanium are undesirable in the eye. Also, it has been found that concentrators made from titanium alloys are of excellent acoustical quality and can work at amplitudes 30 to 40% higher than steel concentrators.[43] However, titanium is comparatively expensive and is more difficult to machine. Therefore, for experimental purposes, the prototype is manufactured using Medical Grade Stainless Steel.

3.3 COMPONENTS OF PROTOTYPE

The manufacture of a prototype can be sub-divided into the *instrument tip*, *stem*, *transducer* and *housing*. Most of the design specifications for these components are directly dependant on the operating frequency. This frequency can only be established after further experimentation on the effect of ultrasound on the lens capsule. The instrument tip, on the other hand, is specified by anatomical and surgical constraints and is not dependant on the operating frequency. A prototype of the tip and a stem of sufficient length was manufactured out of Medical Grade Stainless Steel and is illustrated in Fig. 36.

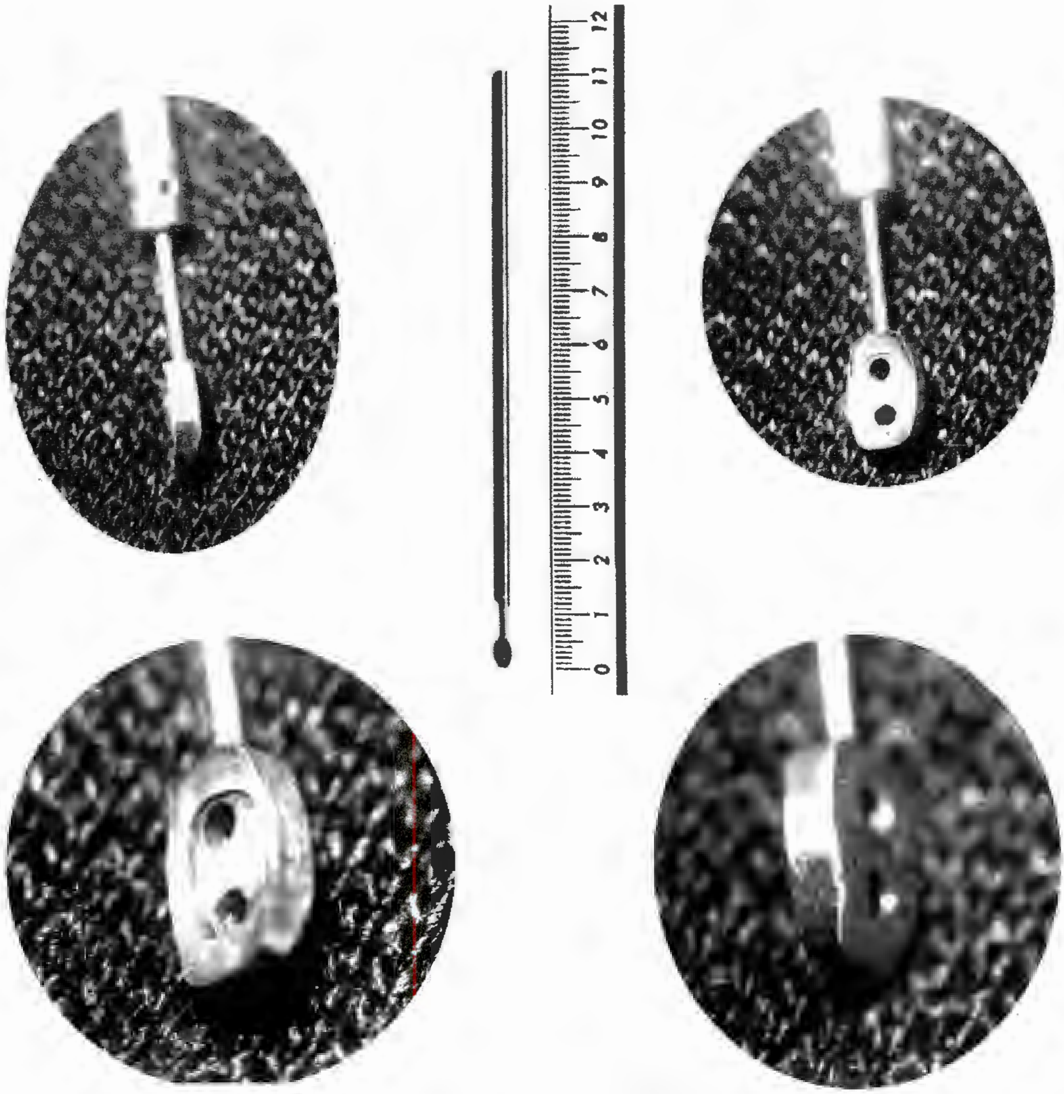


FIG. 36 VIEWS OF THE INSTRUMENT TIP AND STEM PROTOTYPE

CHAPTER FOUR

EXPERIMENTAL INVESTIGATION

4.1 OBJECTIVES OF INVESTIGATION

The investigation of using ultrasonic vibrations as an alternative method to perform a capsulotomy in a cataract surgery has three primary objectives :

1. To numerically simulate resonance of the human lens so that a frequency for perforation of the lens capsule can be predicted or estimated.
2. To observe through experimentation the effect of ultrasound on the lens capsule of human donor eyes and to attempt an anterior capsulotomy.
3. To determine the quality of the capsulotomy margin produced by ultrasound and compare it to current capsulotomy techniques.

4.2 FINITE ELEMENT ANALYSIS

The initial step of this study was to model the human lens using the Finite Element Method of structural analysis and simulate its response at various ultrasonic frequencies. This method, is used routinely in engineering to analyse the behaviour of complex structures. It approximates the structural change within a body by dividing it into *elements*, each governed by a simple polynomial equation. Each element is formed from several *nodes*, which represent the minimal number of points required to define its shape. By enforcing continuity of displacements between adjacent elements, the conformational change of the entire body is represented as a *mesh*.

The accuracy of the finite element solution is dependent upon many factors. The most important of these are :

1. the **number** of elements used to define the finite element mesh
2. the **shape** of the elements relative to the aspect ratio
3. the **type** of element used
4. the **shape function** used to form stiffness and mass matrices
5. the definition of **boundary conditions**
6. the number and location of **degrees of freedom**

To describe a structure for finite element analysis, the geometry, material properties, loading forces, and boundary conditions must be known or approximated. The accuracy of the analytical solution depends directly on the accuracy of these values. Accuracy also depends on the density of the finite element mesh. However, as the mesh is refined, so do the computer resource requirements increase. Therefore, a decision must be made on a justifiable degree of accuracy.

Since the finite element solution is based on a set of approximate functions, a refinement of the function itself also means an increase of the method's accuracy. For instance, if a quadratic displacement of a beam is to be modelled as a single element, then using a higher order quadratic interpolation function for the formulation of the beam element increases the accuracy of the solution. A close approximation of the actual displacement of the beam, using a simple linear displacement interpolation function, can be achieved provided multiple elements to divide the beam are used.

4.2.1 METHOD OF ANALYSIS

The computer analysis of the model is performed using ABAQUS, a commercial finite element analysis program.

The analysis procedure was as follows:

1. define node location
2. choose element types
3. define material and geometric properties
4. define boundary conditions
5. define forcing function
6. suspect submit file for analysis

Since the human lens is generally radially symmetric, it is only necessary to model one quarter of the lens. A simple axi-symmetric model of the lens is made using four-node plane stress elements. The lens is modelled as having two basic structures, namely the anterior capsule and the cortex. The anterior capsule is modelled using only one element throughout the thickness. The cortex is represented with varying degrees of refinement ranging from 600 to 7500 elements. The finite element model used for analysis is shown in Fig. 37.

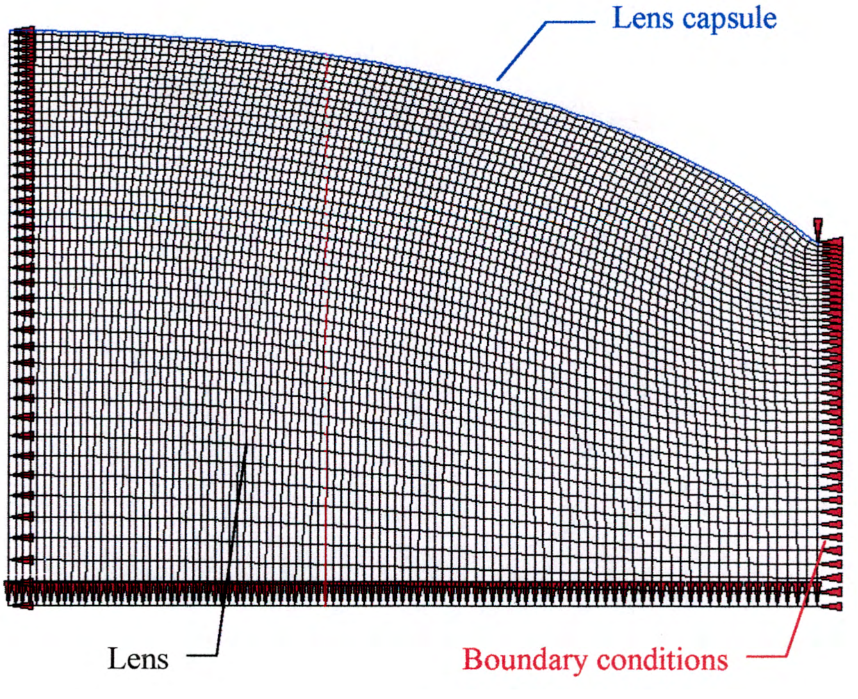


FIG. 37 FINITE ELEMENT MODEL OF ONE QUARTER OF THE HUMAN LENS

Table 4 summarises the geometry and material properties considered for the finite element model. While the geometry, and boundary conditions of the lens can be accurately determined, the material properties are difficult to determine 'in vivo'♣ , and thus these properties are based on 'in vitro' experiments conducted by Fisher[17,19] and Krag[34]. Fisher described the elastic behaviour of the lens capsule as isotropic (Young's modulus is not dependant on orientation of the specimen) and linear. However, Krag showed that there is increasing evidence that the lens capsule exhibits a non-linear behaviour, that is, the mechanical response will depend on the level of strain imposed. In this analysis the deformations are not large and the linear law is used. This assumption is valid as small displacements are generated within the physiological range.

TAB. 4 VALUES USED FOR DEFINITION OF THE FINITE ELEMENT MODEL

	Lens Capsule	*Lens*	*Units*
Young's Modulus°	3 000 000	3 000	N/m^2
Density°	1.0	1.1	kg/m^3
Thickness	0.017	1.47	mm
Width (centre to zonule)	3.25	3.25	mm
Radius of curvature	10	10	mm
Poisson's ratio°	0.47	0.49	

The computer simulation is first performed on small sample problems in order to get familiarised with the program. The mesh is then gradually refined until the results give a reasonable analysis. The model is also run using different element types always keeping the aspect ratio (height vs. width) of the elements close to unity. These results are tabulated in Appendix B.2.

♣ 'in vivo' implies inside the living body while 'in vitro' indicates outside the living body and in an artificial environment

° values are best estimates from review of literature [16,17,18,34]

4.2.2 RESULTS AND DISCUSSION

The final model of the lens is represented by 4000 elements (100 along the base and 40 along the height). The element type that showed the best consistency is a *4-node continuum axi-symmetric* element : CAX4. The result of the numerical program is presented in Fig. 38, and shows the deformation of the model at the specified resonance frequencies within a tolerance of 200 Hz.

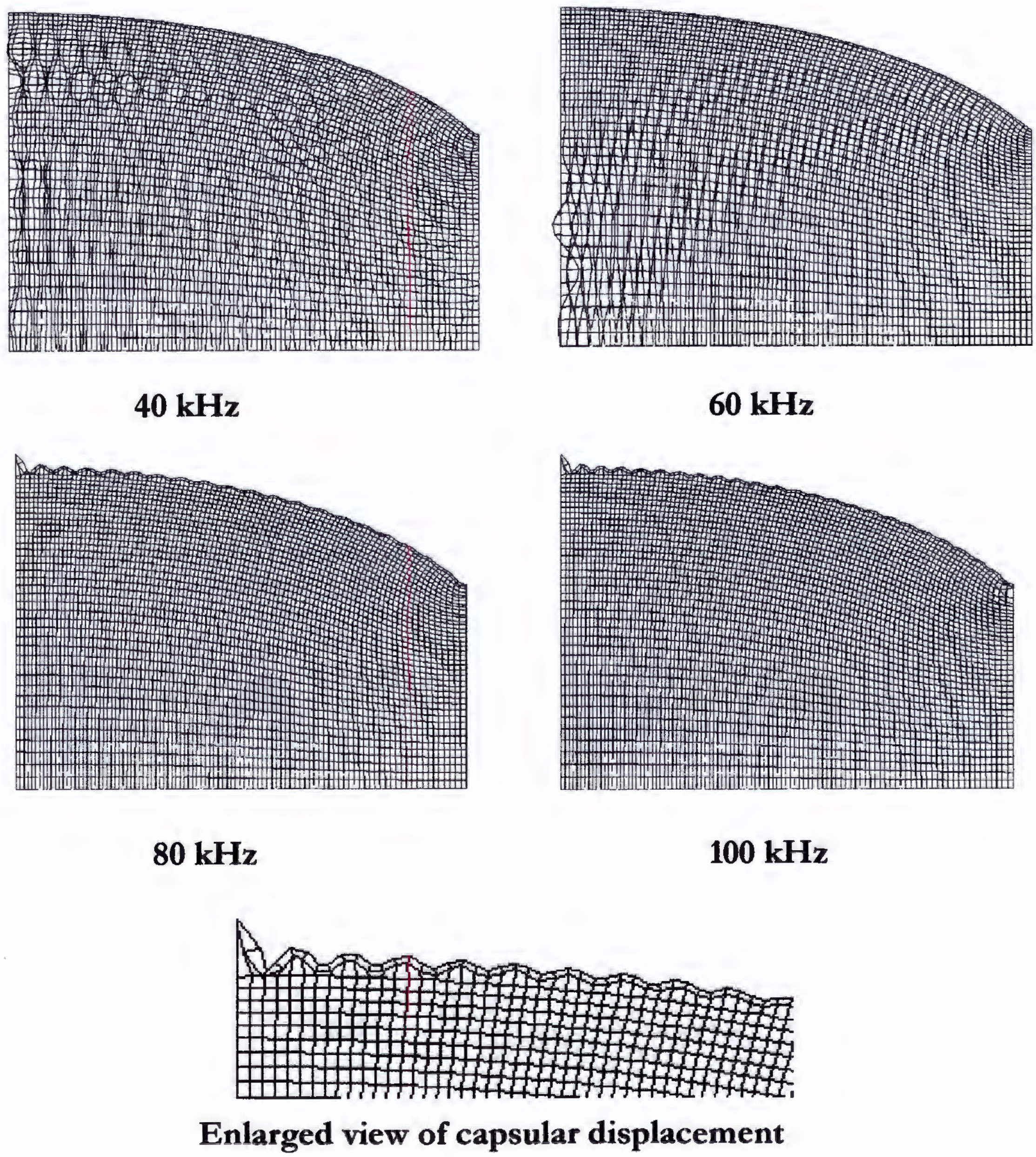


FIG. 38 ABAQUS PLOTS OF THE HUMAN LENS AT VARYING RESONANCE FREQUENCIES

The numerical results illustrated in Fig. 38 shows that :

- At 40 kHz only the lens cortex resonates. As stated in the 'Problem Statement and Objectives' in Section 1.4, the author failed to perform an anterior capsulotomy using the phaco-tip which operates at 40 kHz. In fact, the capsule is fairly safe from any accidental perforation during phacoemulsification, unless the surgeon applies manual pressure directly onto the capsule.

- At 60 kHz, the lens cortex continues to oscillate. This corresponds with the phacoemulsification tool's ability to emulsify the lens over a wide range of operating frequencies, from 30 to 60 kHz.

- From 80 kHz to 250 kHz, the cortex becomes inert whereas and the capsule starts oscillating. It is at these frequencies that the capsule is at resonance and ultrasonic perforation becomes feasible.

If the proposed ultrasonic tool is designed to match the resonance frequency range of the lens capsule, the more-or-less restricted neighbouring area of the capsule in contact with the tool is set into oscillation, while the rest of the capsule remains still. Theoretically, it is at this point that the cellular bonds of the capsule are strained and break along the application of the ultrasound.

4.3 EXPERIMENTAL ANALYSIS ON HUMAN DONOR EYES

The second stage of the investigation involves subjecting the human lens capsule to ultrasonic vibrations at frequencies above 80 kHz. This requires :

- the design of several ultrasonic transducer systems vibrating at specified frequencies
- the perforation of the lens capsule by ultrasonic vibration
- a close observation of the integrity of the perforation

4.3.1 TRANSDUCER SYSTEM

The design of a transducer system is illustrated in Fig. 39 and consists of a *piezoelectric stack*, a *concentrator*, a *backing*, a *housing*, a *centre bolt* and two *O-rings*. The piezoelectric stack is composed of two PZT4 crystals positioned at a displacement node of the mode shape which is also a place of maximum strain, as illustrated in Fig. 27. An inner bolt assembles the transducer system and applies a compressive pre-stress onto the crystals. The O-rings are positioned at nodal points along the system and then the assembled transducer system is placed inside a housing that is mounted on a stand during experimentation.

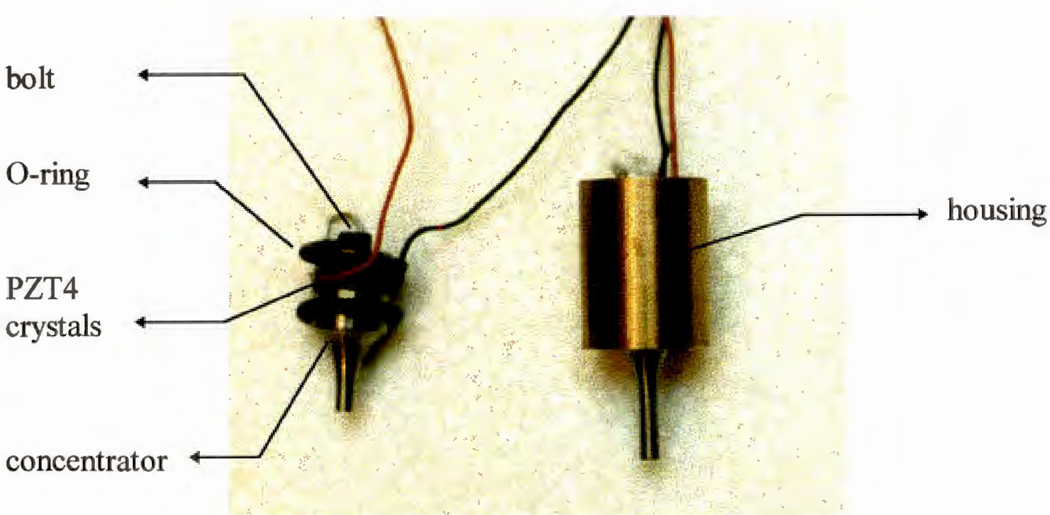


FIG. 39 COMPOSITE PIEZOELECTRIC TRANSDUCER SYSTEM

In collaboration with the CSIR•, three transducer systems were fabricated with the specifications summarised in Table 5. The system, excluding the piezoelectric crystal stack, was manufactured by the workshop of the Mechanical Engineering Department. High toleranced machining ensured that the vibration of the concentrator remained in the long axis, with little lateral motion that could cause flexural (bending) vibrations. The corresponding piezoelectric crystals (PZT4) were produced and assembled by the CSIR. Resonance analysis of each transducer system was tested only after assembly since the natural frequency of a transducer system is dependant on all the dimensions and not only on that of the crystal.

TAB. 5 TRANSDUCER SYSTEM SPECIFICATIONS

	100 kHz	***200 kHz***	***300 kHz***	***Units***
PZT4 diameter	12	12	12	mm
PZT4 thickness	1	1	1	mm
Concentrator tip diameter	3	3	3	mm
Concentrator length	15	29	19	mm
Backing length	6	4	4	mm

The resonance frequency of ultrasonic transducer systems is determined from admittance plots. Each system displays a number of resonance frequencies of varying intensity. The resonance frequencies for the three transducer systems are as follows :

TRANSDUCER DESIGN	*RESONANCE FREQUENCIES*
100 kHz	106 kHz
200 kHz	81.6 and 187 kHz
300 kHz ♦	106 kHz

• Philip Loveday from the *Division of Materials Science and Technology*, **CSIR** (Pretoria, South Africa).

♦ The 300 kHz transducer design could not be tuned successfully to resonate at 300 kHz

4.3.2 EXPERIMENTAL APPARATUS

The test apparatus used to investigate ultrasound application in anterior capsulotomy is shown in Fig. 40.

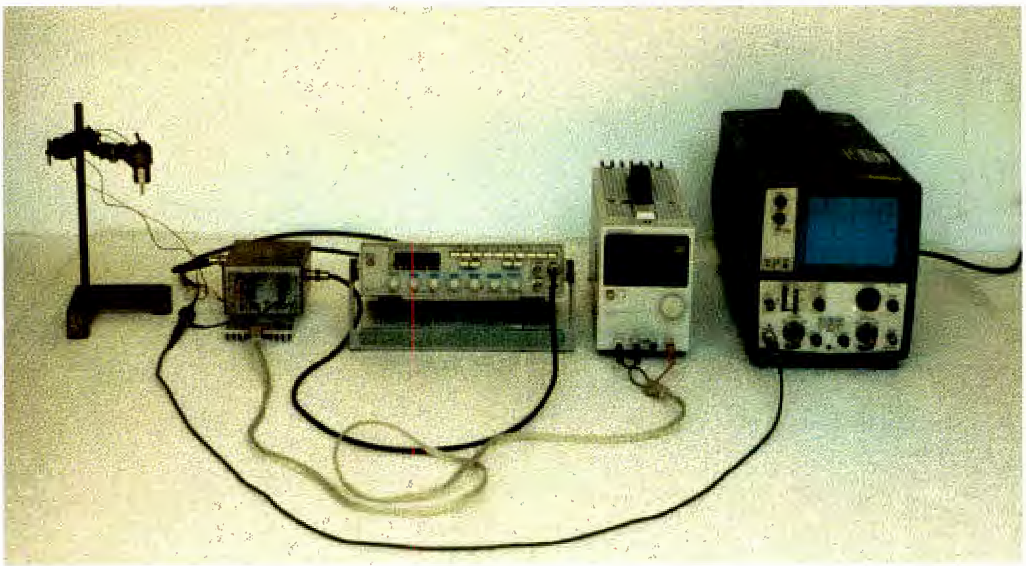


FIG. 40 INSTRUMENTATION USED TO PERFORM EXPERIMENTS

MATERIAL (FROM LEFT TO RIGHT)	*DESCRIPTION*
PZT4 transducer system	100, 200, 300 kHz
Power Amplifier	designed up to 200 kHz
Signal Generator	Kenwood FG-273
Power Supply	Kenwood PWR-361
Oscilloscope	Tektronic-T922 (15 MHz)

When placed in an alternating electric field, the piezoelectric crystals emit vibrations of high force but of small amplitude. Although the concentrator is capable of amplifying the motion of vibration, it is still necessary to maximise the tip's displacement electronically. Since the intensity of the ultrasound generated varies directly with the square of the voltage applied and with the operating frequency, the amplitude of vibrations can be varied continuously by adjusting the driving voltage. The maximum value of the driving voltage is, however, limited to the thickness of the piezoelectric crystal*. The thickness of the crystal is not a parameter that can be varied, as it is directly dependant to its resonant frequency. A power amplifier was built to supply an output of 400 Volts peak to peak for systems operating up to 200 kHz. An internal view of the power amplifier is shown Fig. 41. This amplifier is adequate to drive the piezoelectric crystals of 1 mm thickness.

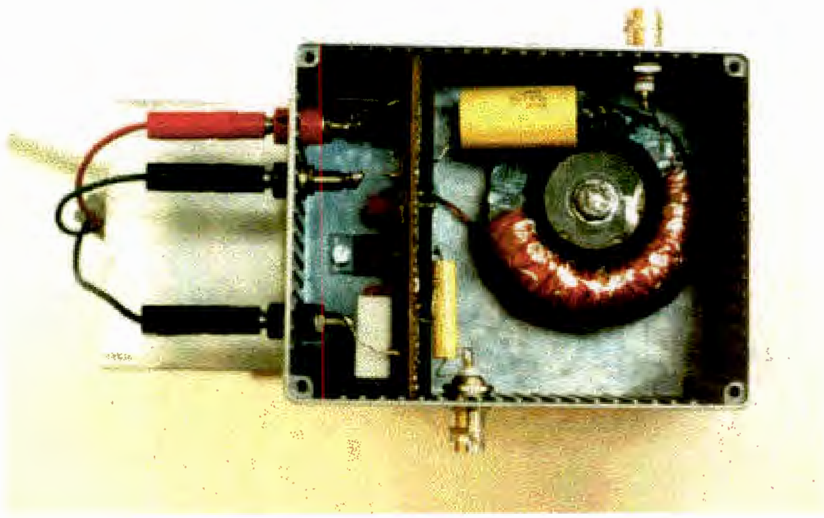


FIG. 41 EXPOSED VIEW OF THE POWER AMPLIFIER

4.3.3 METHOD OF ANALYSIS

The supply of human donor eyes for research purposes was scarce. Therefore, during the initial stages of experimentation, it was thought feasible to use pig eyes. However, the lens capsule was found to be much thicker and without any similarity to the mechanical properties of the human lens capsule. This led to inconclusive experimentation when no perforation was achieved. Therefore, any future experiments depended on the availability of human donor eyes designated for research purposes. In total, 8 human eyes were made available for experimentation by the Eye Donor Bank of South Africa.

* approximately 500 V/mm thickness

The eyes were all analysed within a week of post mortem, since previous work shows that the material properties of the human lens capsule does not change notably between 2 and 9 days post mortem.[17] The cornea was removed, and the iris excised down to its root, permitting 'open sky' access to the anterior lens capsule. This permits clear visualisation of the entire anterior capsule, the anterior zonules, and the ciliary processes as illustrated in Fig. 42.

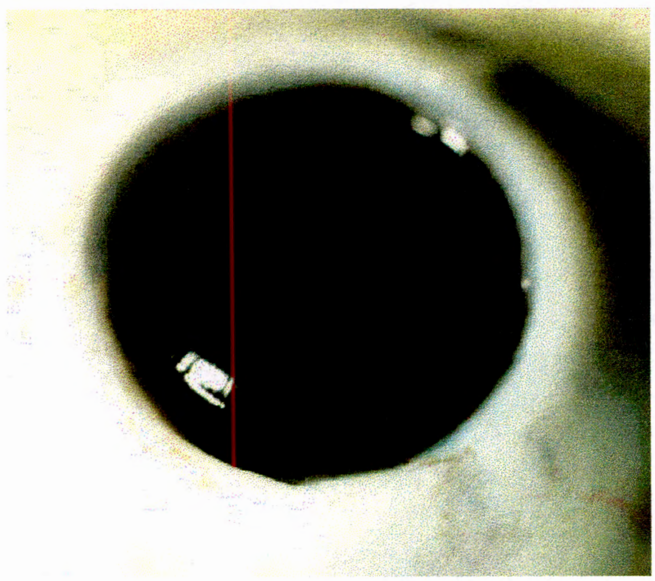


FIG. 42 VIEW OF THE HUMAN LENS AFTER REMOVAL OF THE CORNEA AND IRIS

The piezoelectric transducer system was mounted on a stand and driven at its resonance frequency with maximum driving voltage♦ supplied by means of a signal generator and a power amplifier. The exposed lens was brought up onto the vibrating tip and held stationary for a specified amount of time. After which, the result was observed under a microscope.

♦The maximum voltage was 400 V peak to peak before the sinusoidal signal distorted.

4.3.4 EXPERIMENTAL FREQUENCY OF 81.6 kHz

The first attempt to perforate the lens capsule was at a resonance frequency of 81.6 kHz. Initially, the tip of the concentrator was put into contact with a drop of water. Then, the transducer system was driven at its resonance frequency by tuning the function generator within a narrow bandwidth of less than 10 Hz. The water droplet was observed to become increasingly agitated and with an increase of power to the transducer, the droplet vaporised. This is evidence of the ultrasonic energy and activity present at the tip of the transducer system.

An attempt of perforation was made by setting the capsular membrane into localised vibration for a period of one second, after which the result was examined under a microscope. As illustrated in Fig. 43, a distinct and sharp edged impression was left on the membrane in the shape of the tip. However, there was great difficulty in judging whether the capsule had been breached.

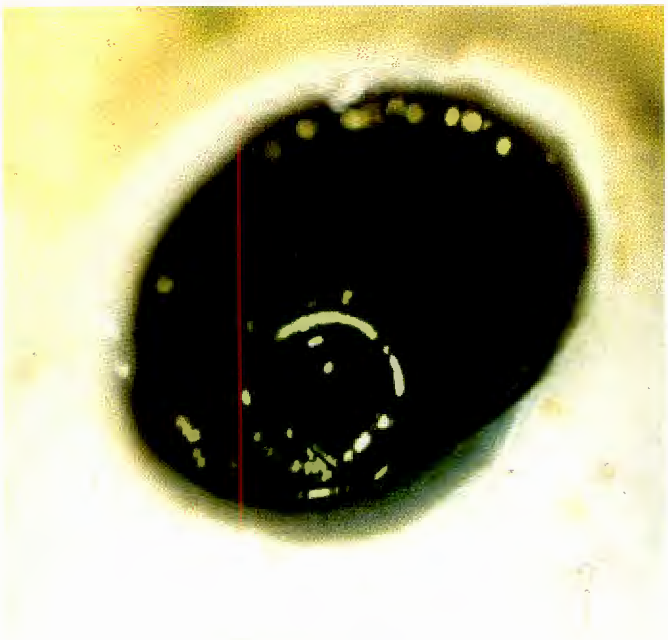


FIG. 43 CIRCULAR INDENTATION VISIBLE ON THE LENS CAPSULE

Gentle probing with a needle confirmed that the lens capsule had not been perforated. Inspection under the microscope revealed the presence of gas bubbles and clouding of the tissue in the area of the impression. These irregularities are shown in Fig. 44. An astounding observation was made when discovered that the cortex had been denatured and not the lens capsule.

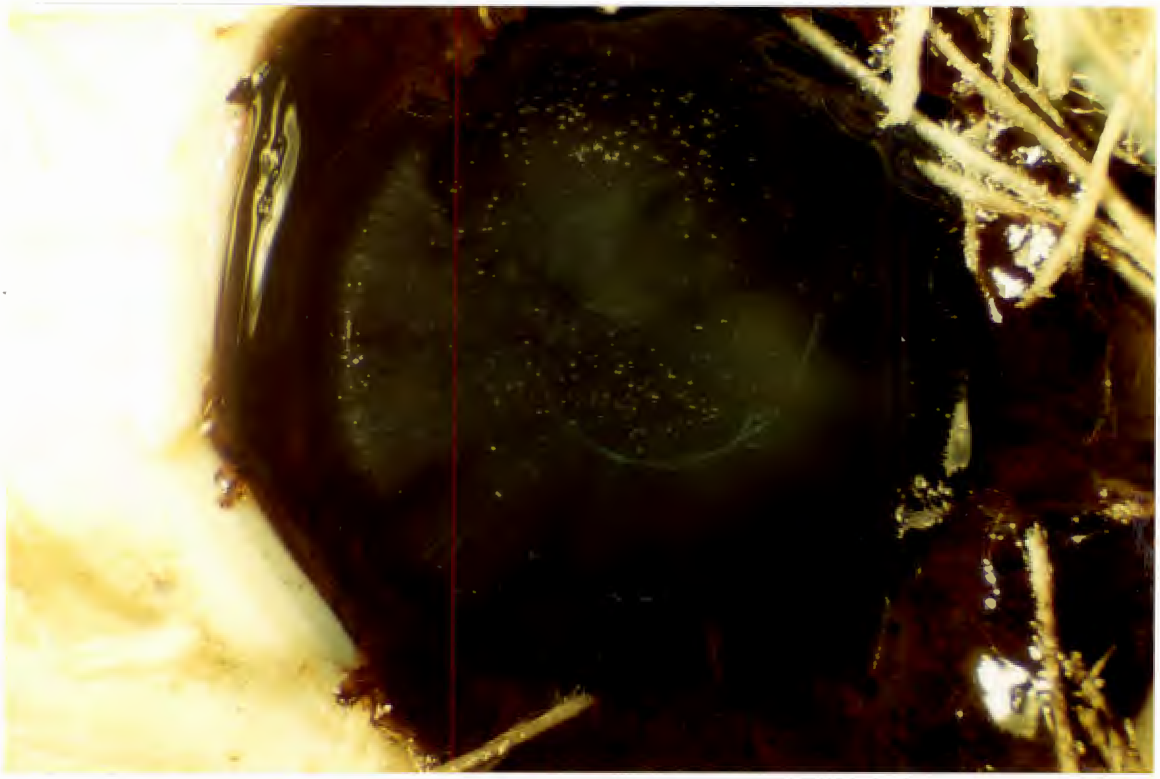


FIG. 44 HUMAN LENS AFTER ONE SECOND OF ULTRASONIC EXPOSURE AT 81.6 KHZ*

A second attempt to perforate the lens capsule was made by applying the ultrasound for twice as long, namely two seconds. As shown in Fig. 45, this resulted in the formation of larger bubbles and denser clouding of the lens cortex in the area of the ultrasound application.

With a longer application of about 10 seconds, the lens capsule was ultimately perforated. This capsular perforation, as illustrated in Fig. 46, was triangular in nature and exhibited several tears.

* The effect of the ultrasound on the lens is enhanced by these colour photographs which could not be represented in an other form

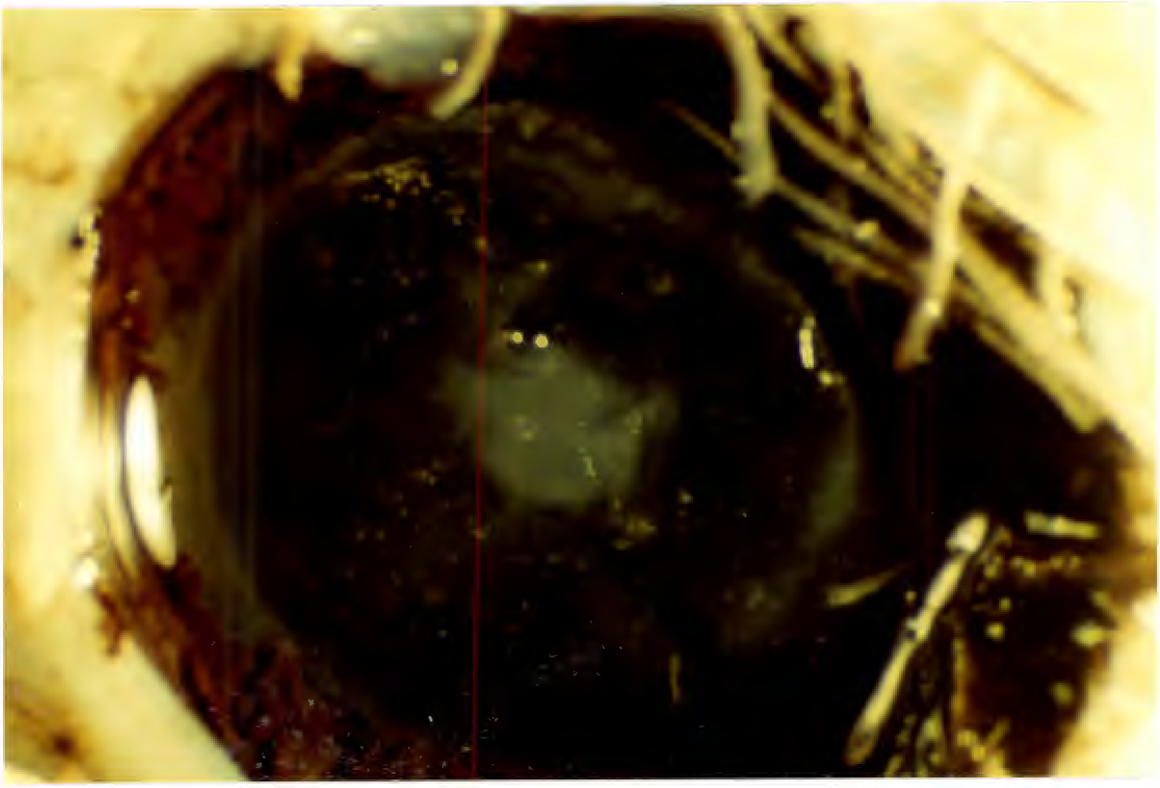


FIG. 45 HUMAN LENS AFTER TWO SECOND EXPOSURE TO ULTRASOUND AT 81.6 KHZ

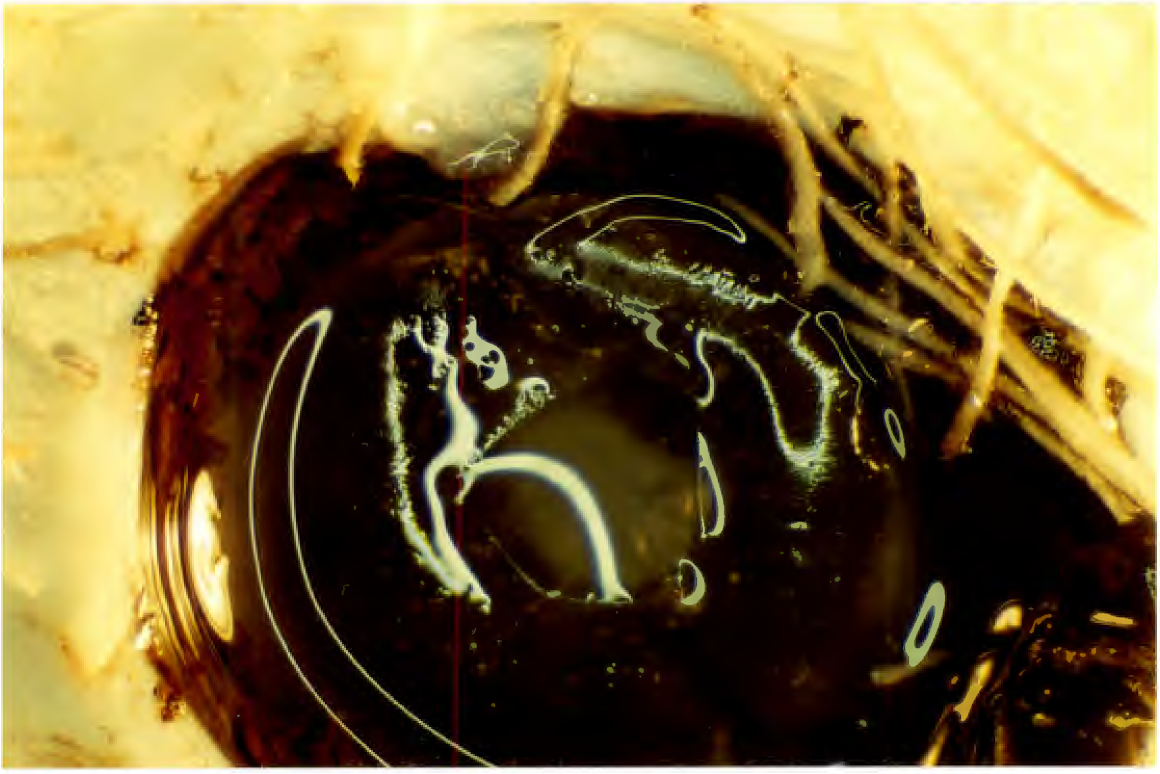


FIG. 46 PERFORATION OF THE LENS CAPSULE AFTER 10 SECOND EXPOSURE TO ULTRASOUND AT 81.6 KHZ

Since perforation had not been accomplished in the initial experiments, ultrasound as the sole factor of capsular perforation was questionable. Additional observations to the conditions involved during perforation, included a definite temperature increase at the concentrator's tip. Also, a direct pressure applied onto the lens capsule by the operator may be questioned. Subsequent measurements using a thermocouple indicated that the temperature at the tip rises up to 160 °C after several minutes of operation. This is in full accordance with the temperature used in diathermy capsulotomy[27,49], a factor that can not be overlooked.

It was important to isolate the temperature factor and to test it individually. A soldering iron with a tip diameter of 2.5 mm was heated to 160 °C using a Variac transformer and applied onto a fresh lens capsule. Instantly, the lens capsule in contact with the tip disintegrated and the underlying lens cortex coagulated. The denatured cortex is illustrated in Fig. 47.

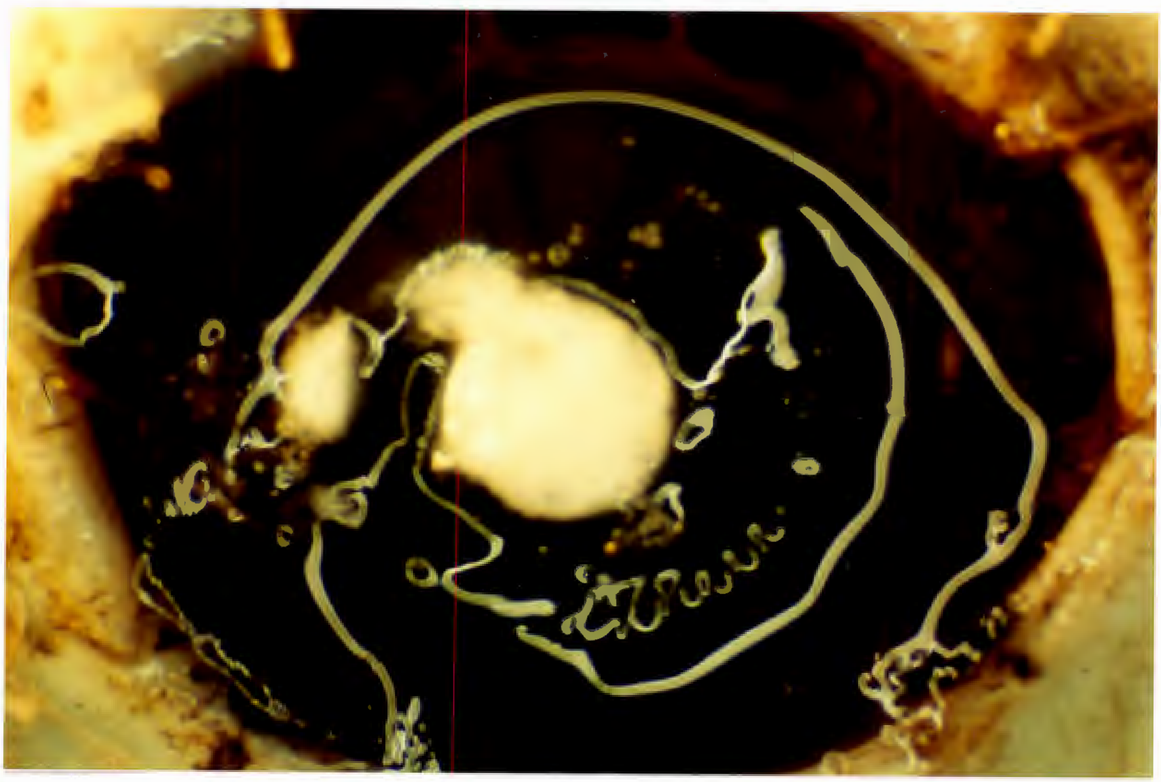


FIG. 47 TEMPERATURE EFFECT ON THE LENS CAPSULE AND CORTEX

DISCUSSION

The following points can be made from the results of the experimentation using 81.6 kHz frequency :

- The temperature at the tip was negligible during the first two unsuccessful perforation attempts. Also, the pressure applied to the lens capsule was just sufficient enough for force coupling. Since these two factors are not contributing to the formation of bubbles and the clouding of the tissue, it can be deduced that ultrasound is responsible for the denaturing.

- The characteristic clouding of the cortex is due to the sound field near the contacted region of the capsule being highly non-uniform. This causes an acoustic radiation torque to be exerted on small structures present on the other side of the vibrating membrane, thereby denaturing the cortex.

- The bubbles present in the cortex may be explained by cavitation occurring in the cortex when ultrasound emits cycles of compressions and decompression. During a cycle of expansion the molecules in the cortex are separating enough to denature the tissue and create gas cavities.

- By comparing Fig. 46 and Fig. 47, it is evident that coagulation of the cortex is not as evident during ultrasonic perforation as that observed during thermal perforation. This is because the ultrasonic perforation was performed below the well established temperature of 160 °C used in diathermal capsultomy[49]. Therefore, the perforation of the lens capsule as described above is not due to temperature but must be due to ultrasonic vibrations. In fact, it appears that the continued application of ultrasound on the lens capsule weakens areas of the membrane. Further vibrations induce a torque on the membrane, thereby initialising tears at the point of contact and the applied pressure for force coupling is sufficient to create the resulting triangular opening observed in Fig. 46.

4.3.5 EXPERIMENTAL FREQUENCY OF 106 AND 187 kHz

Attempts to perforate the lens capsule at 106 and 187 kHz failed. Although, signs of clouding was present, the magnitude of activity was small compared to that at 81.6 kHz. When the concentrator tip was placed in contact with a water droplet, little sonic energy was observed at the resonance frequencies.

DISCUSSION

- At high frequencies the amplitude of the oscillations decreases. This is because the particles are forced to vibrate faster and require a higher energy input to maintain the same amplitude. It is felt that at 106 and 187 kHz, little sonic energy is emitted and the amplitude of vibration is too small to disturb the capsule and the cortex in a notable manner.

- Although the theoretical analysis shows the capsule at resonance, both high acceleration and amplitude of ultrasound vibrations are required to perforate the lens capsule. The concentrator performed at its optimum amplification capacity. However, the crystal, the thickness of which is fixed at 1 mm, limits the driving voltage to 400 V, a continuous drawback during the experimentation. A higher voltage than 400 V requires a thicker crystal which as explained in Section 4.3.2 is not possible.

4.3.6 CLOSING COMMENTS

Although the perforation of the capsule observed in Fig. 46 occurred frequently during the experimentation, it was always irregular in shape.

Also, it was observed that the lens capsule looses its surface tension upon perforation. This makes a second perforation impossible without the presence of force coupling and violates the conceptual design presented in Chapter 3 which creates two perforations on the lens capsule. This concept was developed in order to comply with the design requirement of performing a 5 mm diameter capsulotomy through a 3.2 mm scleral incision.

CHAPTER FIVE

CONCLUSIONS

The purpose of this thesis was to show (1) that there is a need in cataract surgery for an alternative anterior capsulotomy technique and (2) how ultrasound can be applied to overcome the difficulties experienced with anterior capsulotomy techniques. The question lies in whether ultrasound is capable of creating a smooth anterior capsulotomy. Currently, ultrasound is used cortex quite effectively to fragment the lens. However, experimental investigation conducted on human lenses indicates that ultrasound at frequencies of 40, 81.6, 106 and 187 kHz, is unable to easily fragment the lens capsule. It is evident, therefore , that there is a marked distinction between the easily fragmented lens cortex and the rigid lens capsule.

The lens cortex is composed of lens fibres unlike the capsule which is primarily an arrangement of densely packed collagen microfibrils. The more a material is composed of collagen, the greater is its material strength. The structural quality of the membrane is determined by the collagen type, its quantity and organisation. Along with other tissues with a high constitution of collagen, such as vessel structures, tendons, and ligaments, the capsule is a tissue that fragments poorly.

Also, the lens capsule has a series of collagen lamellae that run parallel to the surface and at right angles to the zonular insertions. This arrangement causes a tear to run along the natural fibrillar fault lines, a material property respected by the CCC capsulotomy technique. Other techniques that do not involve tearing (diathermy capsulotomy) lead to an edge with differing resistance to breakage, and a force applied to this margin will result in a radial tear. Surgical manipulations extend this tear at any stage in the operation (a) during its creation; (b) during emulsification of the nucleus or (c) during implantation of the IOL.

The only capsular perforation was achieved at 81.6 kHz and showed a highly irregular contour with several tears. However, this perforation was only performed after a prolonged application of ultrasound. As a result of this, a rise in temperature at the tip of the concentrator was sufficient to change the material properties of the lens capsule. As stated in Section 2.4.4, at temperatures above 65 °C, the capsule becomes rubbery with a decrease in Young's modulus. This is a change of state that is not accounted for in the numerical analysis, which simulates the lens at natural conditions (i.e. body temperature). The change in material properties may have been the key reason for the repeated failure to perforate the capsule.

A successful ultrasonic capsulotomy requires (1) ultrasonic vibrations at the resonance frequency of the lens capsule and (2) high acceleration and amplitude of vibrations for fragmentation purposes. The present experimental set-up is optimised according to specific frequency requirements. Due to crystal limitations, the amplitude was not sufficient to cause tissue destruction. Therefore, the concept that ultrasound can create a smooth perforation on the lens capsule is highly questionable at this stage.

Although it is not the scope of this thesis to support an alternative anterior capsulotomy technique, it can be concluded with confidence that the result produced by the CCC technique is by far superior to the ultrasonic perforation in this present investigation.

CHAPTER SIX

RECOMMENDATIONS

Based on the findings of this study, the following recommendations can be made ;

- The ultrastructure of the lens capsule has been detailed in many publications. However, the mechanical role of these elements has not been conclusively established. The tools for measuring these processes are available, yet results of studies are still contradictory and based on many assumptions. There is a gap in knowledge concerning mechanical properties of the lens capsule. This must be covered before the vibration patterns of the lens capsule can be accurately known.

- Since ultrasound is a threat to non-target tissues such as the corneal epithelium, further studies into this biological effect must be investigated.

- The outcome of the investigation into ultrasound application was not acceptable. Therefore, further development of the ultrasonic capsulotome is terminated.

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APPENDIX A
PARAMETERS OF THE EYE

APPENDIX B
FEM PROGRAM AND RESULTS

APPENDIX C
ULTRASONIC DESIGN SKETCHES

APPENDIX A

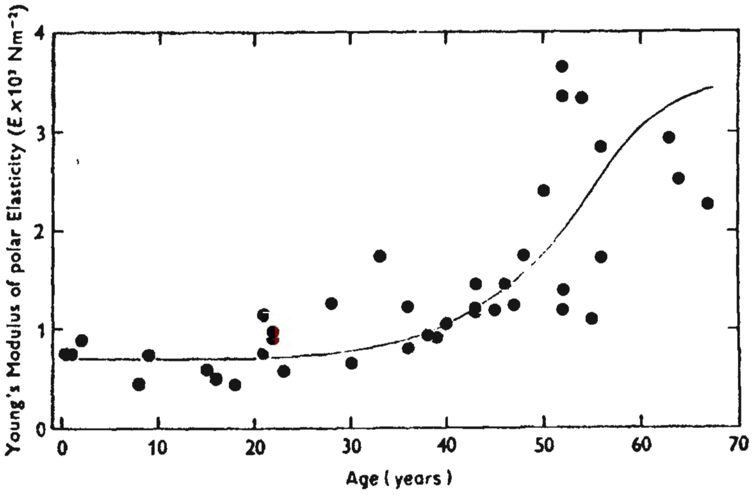
PARAMETERS OF THE EYE

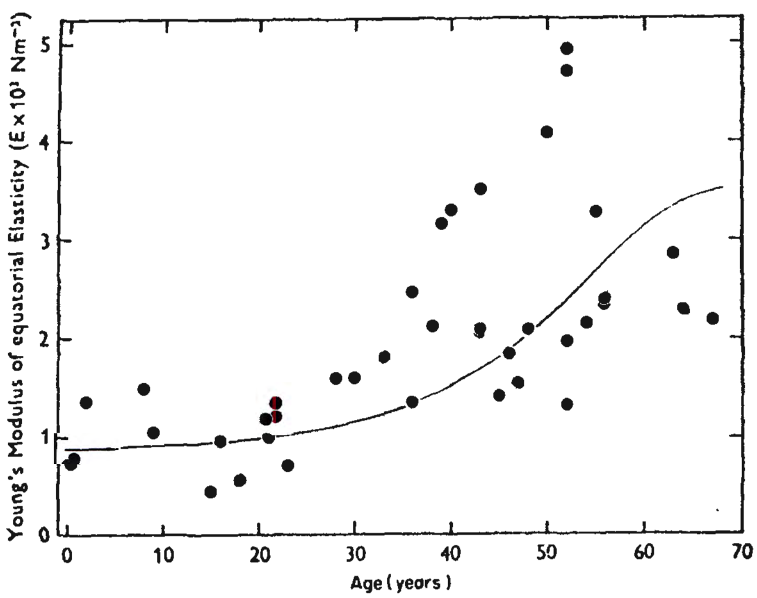
A.1 LENS PARAMETERS

PHYSICAL [35]	*Adults*	*Range*	*Units*
Equatorial diameter	9.5	9 to 10	mm
Axial thickness	5	maximum	mm
Volume	244	maximum	ml
Mass	266	maximum	mg
Radius of curvature			
Anterior	10	8 to 14	mm
Posterior	6	4.5 to 7.5	mm

PHYSICAL [45]	*birth*	*10 - 20 years*	*20 - 40 years*	*90 years*	*Units*
Equatorial diameter	5	8.5	9	9.6	mm
Axial thickness	4	3.5	3.5	4.9	mm
Volume	90	148	162 - 177	238	ml
Mass	92	153	172 - 190	258	mg

MECHANICAL [18]	*Birth*	*60 years*	*Units*
Poisson's ratio	0.49		
Young's modulus			
Polar	750	850	N/m^2
Equatorial	3 000	3 000	N/m^2



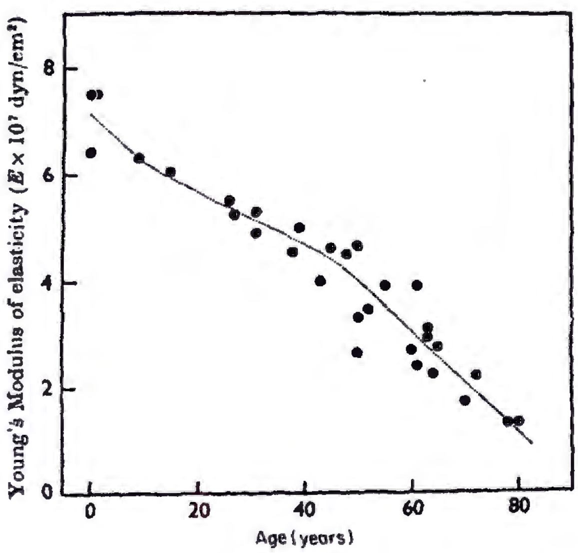


YOUNG'S MODULUS OF POLAR ELASTICITY AND EQUATORIAL ELASTICITY VERSUS AGE OF THE HUMAN LENS [16]

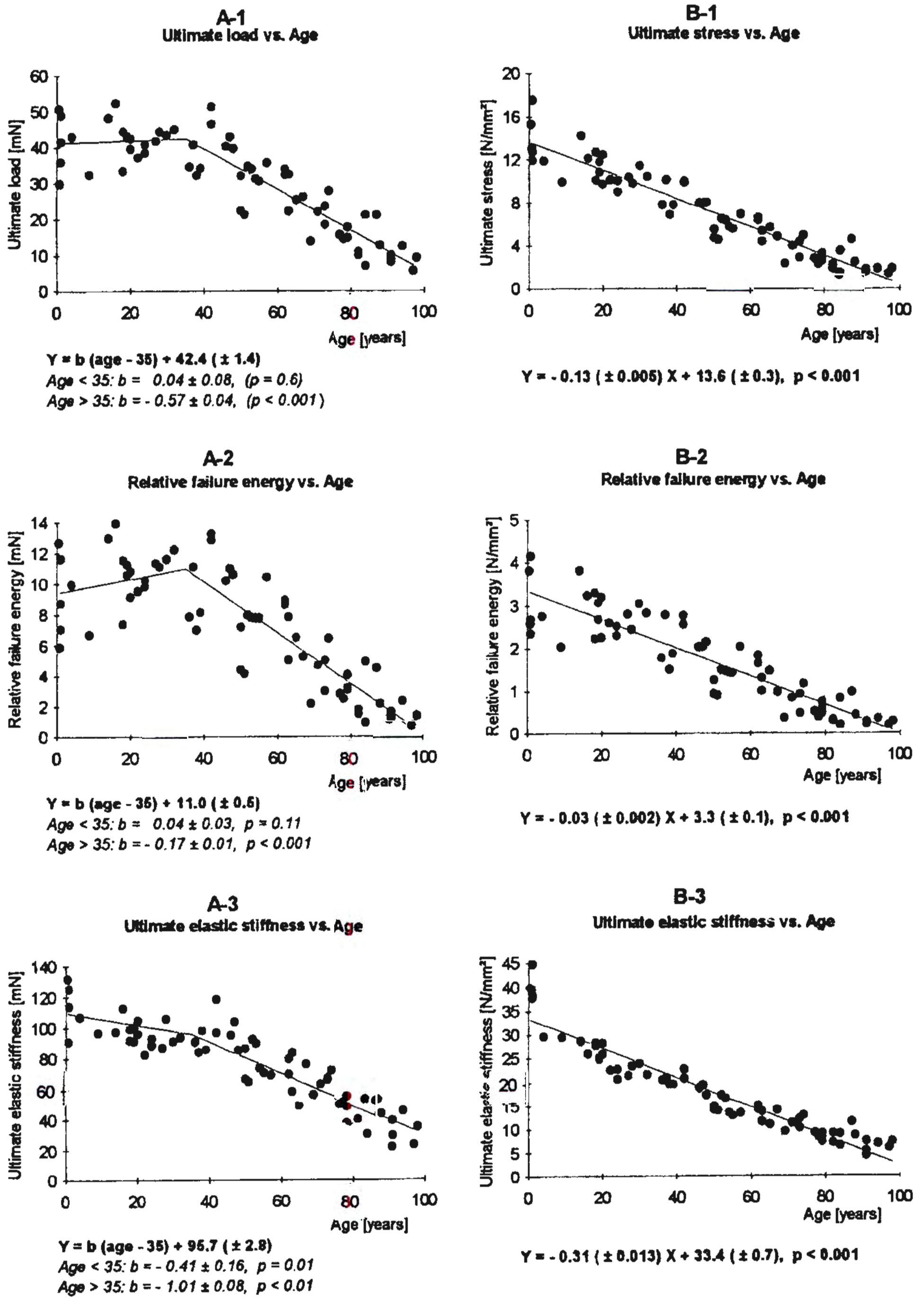
A.2 LENS CAPSULE PARAMETERS

PHYSICAL – Capsule Thickness [32]	*5 years*	*35 years*	*70 years*	*Units*
Anterior pole	8	14	14	μm
Anterior periphery	12	21	21	μm
Equator	7	17	13	μm
Posterior pole	2	4	2.5	μm
Posterior periphery	18	23	9	μm

MECHANICAL [17,28,33,34]	*10 years*	*60 years*	*Human Range*	*Porcine Range*	*Units*
Thickness			11 to 33	50 to 60	μm
Bulk modulus	30	15	44.8 to 4.4	31.5 to 10	N/mm^2
Young's modulus	6	3			N/mm^2
Ultimate tensile stress	12	6	17.5 to 1.5		N/mm^2
True ultimate stress			31.8 to 2.1		N/mm^2
Extensibility	91	66	108 to 40	89 to 66	%



YOUNG'S MODULUS OF ELASTICITY VERSUS AGE OF THE HUMAN LENS CAPSULE



INDIVIDUAL DATA POINTS OF ULTIMATE LOAD DATA (A) AND ULTIMATE STRESS DATA (B) VERSUS AGE OF THE HUMAN LENS CAPSULE [34]

APPENDIX B

FEM PROGRAM AND RESULTS

B.1 ABAQUS PROGRAM

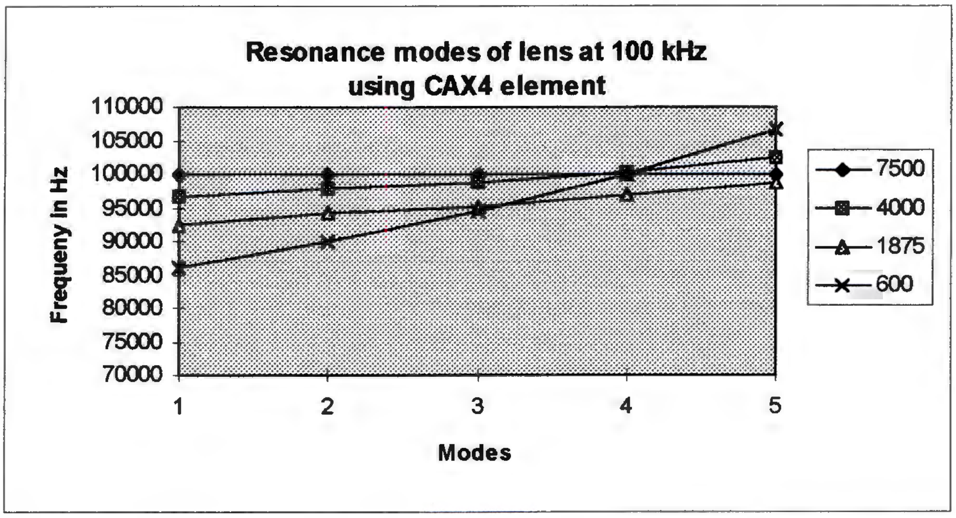
```
**------------------------------------------------------------------------
**                FREQUENCY ANALYSIS OF THE LENS
**                     MEMBRANE IN ABAQUS
**------------------------------------------------------------------------
**
*HEADING
Frequency Analysis Of Lens
*RESTART,WRITE,OVERLAY
*NODE,NSET=NUCLEUS
      1, 0.00E+00, 0.00E+00
   201, 3.25E-03, 0.00E+00
80001, 0.00E+00, 2.00E-03
80201, 3.25E-03, 2.00E-03
*NODE, NSET=CAPSULE
81001, 0.00, 2.017E-03
81201, 3.25E-03, 2.017E-03
*NGEN,NSET=NUCBOT
 1, 201, 1
*NGEN,NSET=NUCTOP
80001, 80201, 1
*NFILL,NSET=NUCLEUS,BIAS=1.01
NUCBOT,NUCTOP,80,1000
*NGEN,NSET=CAPTOP
81001, 81201, 1
*NFILL,NSET=CAPSULE
NUCTOP,CAPTOP,1,1000
**
```

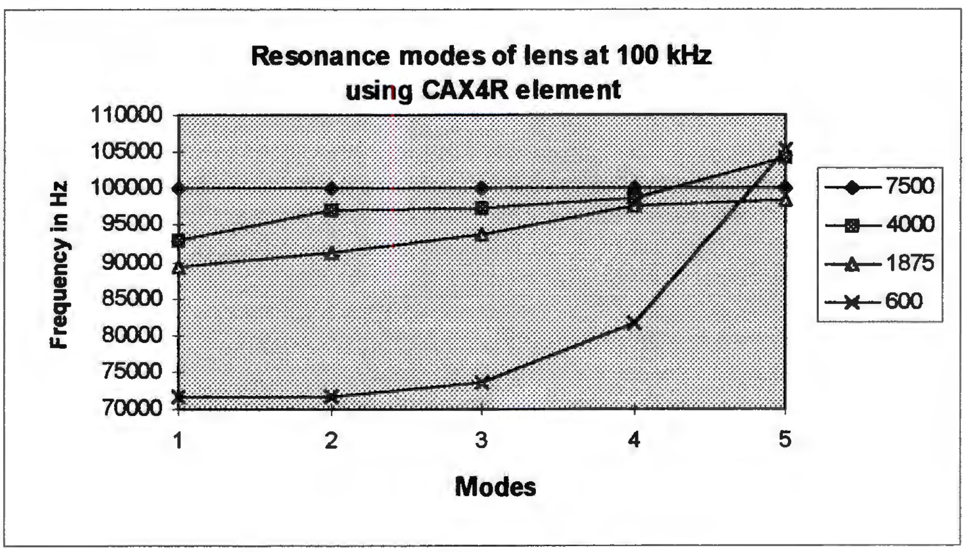
```
*NSET,NSET=SYMM,GENERATE
1, 81001 ,1000
*NSET,NSET=OUTER,GENERATE
201, 81201, 1000
*NSET,NSET=BASE,GENERATE
1, 201, 1
**
**-----------------------------------------------------------------
*ELEMENT,TYPE=CAX4H,ELSET=NUCLEUS
1, 1, 3, 2003, 2001
*ELGEN,ELSET=NUCLEUS
1, 100, 2, 1, 40, 2000, 1000
*ELEMENT,TYPE=CAX4H,ELSET=CAPSULE
300000, 80001, 80003, 81003, 81001
*ELGEN,ELSET=CAPSULE
300000, 100, 2, 1
**
*SOLID SECTION,ELSET=NUCLEUS,MATERIAL=NUCLEUS
*MATERIAL,NAME=NUCLEUS
*ELASTIC
3.00E+03, 0.49
*DENSITY
1.10E+03
*SOLID SECTION,ELSET=CAPSULE,MATERIAL=CAPSULE
*MATERIAL,NAME=CAPSULE
*ELASTIC
3.00E+06, 0.47
*DENSITY
1.00E+03
**
**-----------------------------------------------------------------
*STEP,NLGEOM,INC=100
*STATIC
0.5,1.0
*BOUNDARY
SYMM, 1, 1
OUTER, 1, 1
80201, 2, 2
```

```
81201, 2, 2
BASE, 2, 2, 0.543E-03
*EL PRINT,FREQUENCY=0
*NODE PRINT, FREQUENCY=0
*MODAL FILE
*ENDSTEP
**
**------------------------------------------------------------------
*STEP,NLGEOM
*FREQUENCY
5, , 1600000000, , 75
*EL PRINT,FREQUENCY=0
*NODE PRINT, FREQUENCY=0
*MODAL FILE
*ENDSTEP
**------------------------------------------------------------------
```

B.2 RESONANCE AT 40 AND 100 kHz

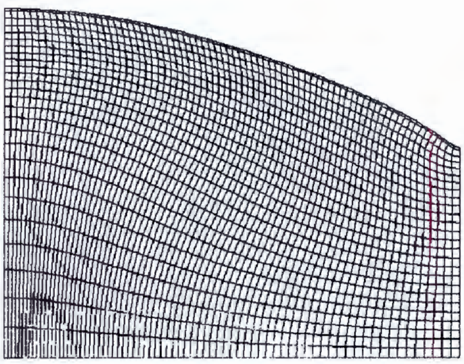
		ELEMENT TYPE USED AT 40 kHz			ELEMENT TYPE USED AT 100 kHz	
MESH SIZE	MODE NUMBER	CAX4	CAX4R	CAX4H	CAX4	CAX4R
7500 elements	1	39988	39988	39988	99907	99982
	2	39990	40000	40000	99974	99988
	3	39996	40011	40011	100009	100025
	4	40000	40012	40012	100045	100029
	5	40004	40017	40017	100097	100069
4000 elements	1	39983	39989	39983	96597	92841
	2	39998	39996	39998	97883	97072
	3	40002	40010	40002	98886	97298
	4	40012	40013	40012	100386	98656
	5	40013	40024	40013	102546	104171
1875 elements	1	39835	39869	39954	92397	89333
	2	39836	39930	39982	94273	91264
	3	39895	39940	40022	95059	93775
	4	39963	39982	40063	97029	97670
	5	39980	39999	40083	98793	98544
600 elements	1	37789	34314	33600	86092	71614
	2	38551	37178	34300	90034	71688
	3	40457	37924	34700	94524	73672
	4	41928	41516	36300	99888	81619
	5	42582	45258	37700	106538	105439



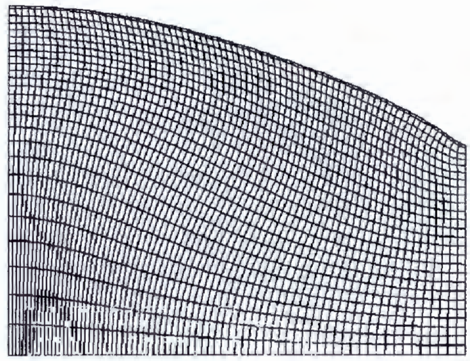


B.3 FIRST NATURAL FREQUENCIES OF THE LENS

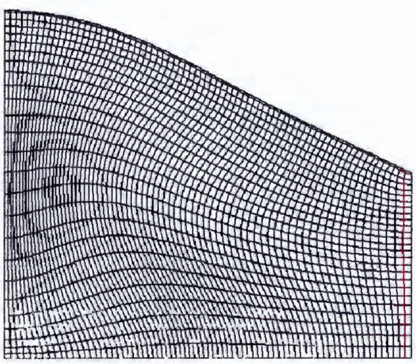
Mesh Size	Mode Number	CAX4	CAX4R	CAX4H
	1	328	328	328
4000	2	410	411	410
elements	3	487	445	487
	4	518	483	518
	5	596	485	596



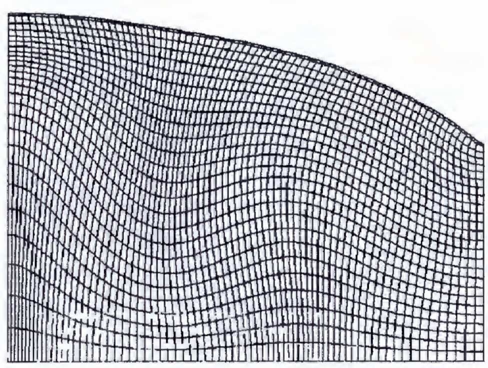
328 Hz



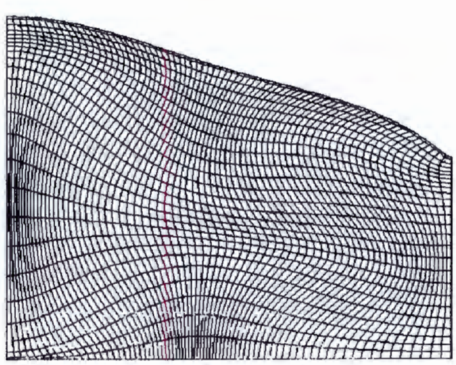
410 Hz



487 Hz



518 Hz

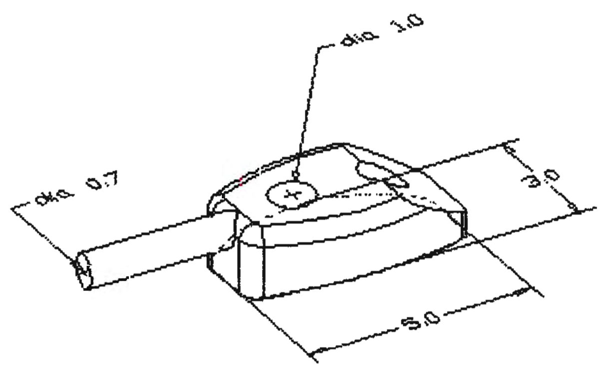


596 Hz

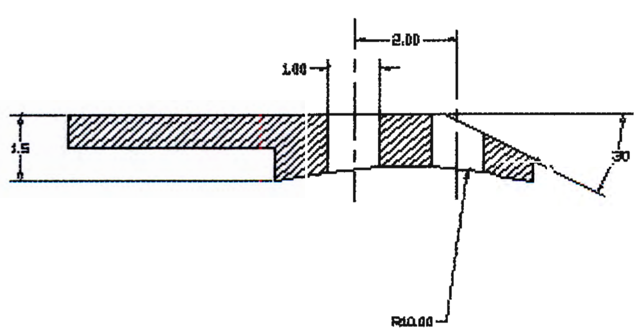
APPENDIX C

ULTRASONIC DESIGN SKETCHES

C.1 DRAWINGS OF ULTRASONIC TIP

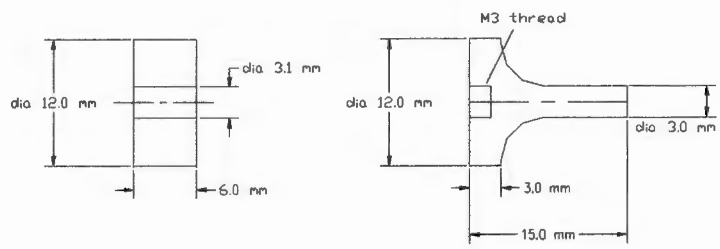


All dimensions in mm

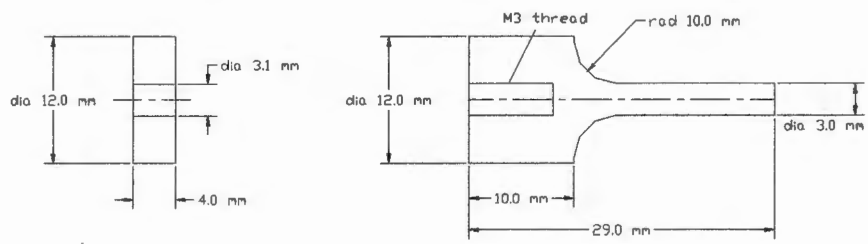


C.2 DRAWINGS OF BACKINGS AND CONCENTRATORS

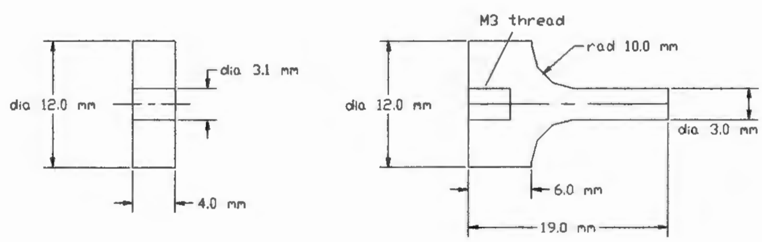
100 kHz



200 kHz



300 kHz

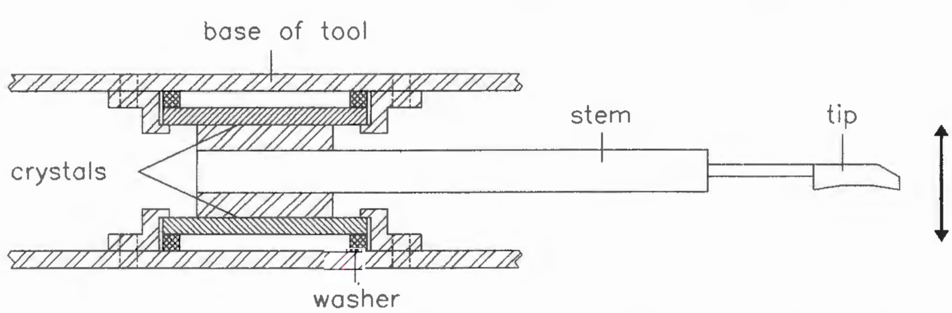


Notes :

Backmass matl = Brass
Amplifier matl = Steel
Centre bolt = Steel M3

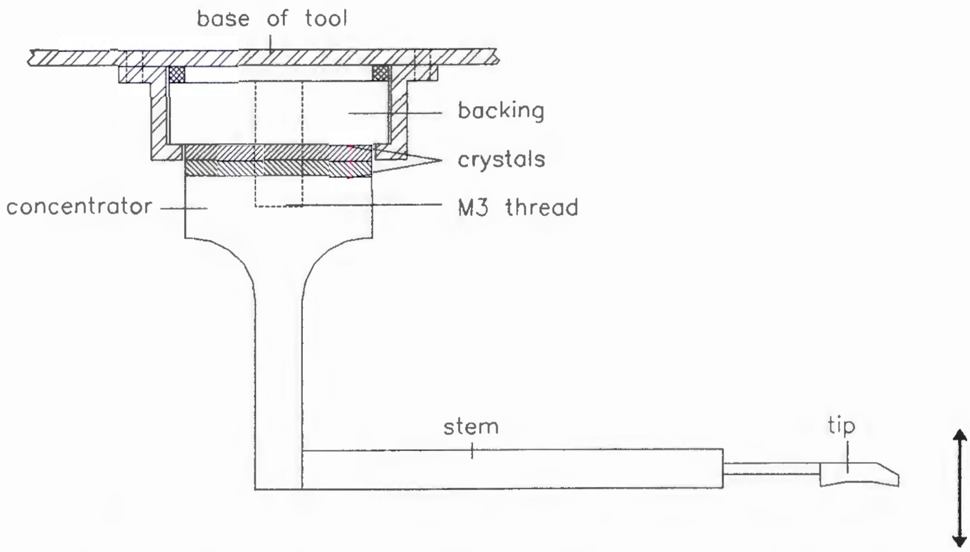
C.3 CONCEPT DESIGNS OF ULTRASONIC CAPSULOTOME

1)



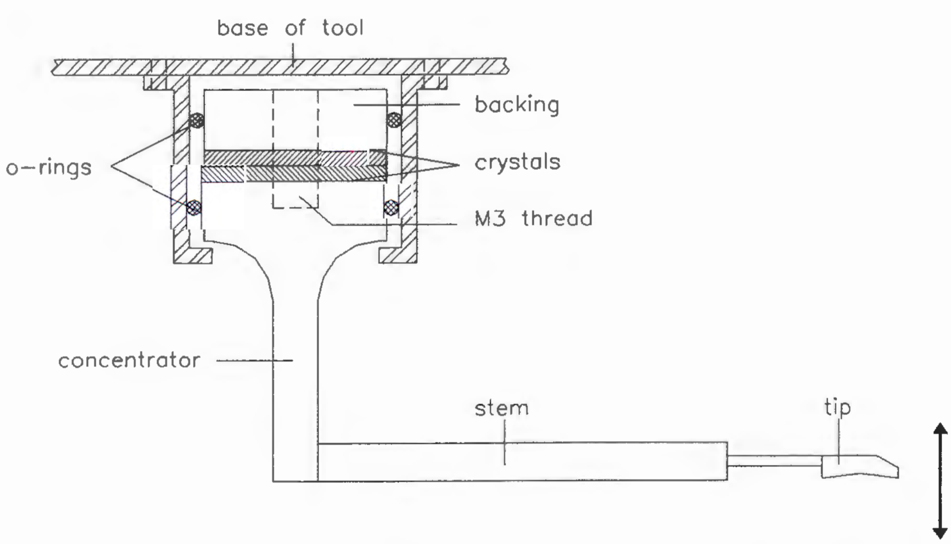
Design 1 has two piezoelectric crystals placed on either side of the stem. When an alternating voltage is supplied to the crystals, the upper and lower crystals begin to shrink and dilate in opposite directions thereby sharing the load of the tool stem and tip.

2)



Design 2 includes a concentrator whose function it is to intensify the amplitude of the ultrasonic vibrations. The stem is at right angles to the concentrator in order to translate vibrations into a vertical axis. The system is attached to the hand tool by securing the backing .

3)



Design 3 also consists of a concentrator and backing. However, the entire system is located in the housing of the tool by two O-rings set at nodal points of vibration mode along the transducer system. Again,, the stem attaches to the concentrator at right angles.